

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	06 OCT 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/8/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11251243]
2.	Birth Date:	(b) (6) 2003
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Dec/8/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal allergies]
	Start Date:	UNK/UNK/2004
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tonsillitis]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tonsillectomy]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

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: 10-Oct-2020 16:04

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Dec/8/2020
2.	Weight:	[132.0]
3.	Unit:	LB
4.	Height:	[65.0]
5.	Unit:	in
6.	Body Mass Index:	[22.0]

Vital Signs Details

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

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Dec/8/2020
2.	Randomization Number:	[112420]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/8/2020
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	[BR7CHW]
5.b	Sample ID	[BR7CHX]
5.c	Sample ID	[BMPGMT]
5.d	Sample ID	[BS5H14]

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/8/2020
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	[BPTN04]
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090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/8/2020 18:03
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

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/30/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Dec/30/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/30/2020
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	[BPTN0Y]
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090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[Form Comments](#)
[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	Not Done _____	Comments
2.	Treatment Name	Not Done _____ []	Comments
3.	Formulation:	Not Done _____	Comments
4.	Dose Date Time:	Not Done _____ //	Comments
5.	Anatomical Location:	Not Done _____	Comments
6.	Body Side:	Not Done _____	Comments
7.	Route:	Not Done _____	Comments
8.	Actual Dose:	Not Done _____ []	Comments
9.	Unit:	Not Done _____	Comments
10.	Timeframe Subject Was Observed	Not Done _____	Comments
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done _____	Comments

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/29/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)
[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	Not Done _____	Comments
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
3.	Injection Site Location:	Not Done _____	Comments
4.	Injection Site Body Side:	Not Done _____	Comments
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	Comments
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	Comments
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	Comments

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/29/2021
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	[BPTN6T]
5.b	Sample ID	[BPTN6V]
5.c	Sample ID	[BMPGRC]
5.d	Sample ID	[BS5H3K]

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
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090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Grade 3 Pain at Injection site	Dec/9/2020 UNK:UNK	NO End Date Time: Dec/9/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Grade 3 Headache	Dec/9/2020 UNK:UNK	NO End Date Time: Dec/9/2020 UNK:UNK	Repeating Pages

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Grade 3 Pain at Injection site]
4.	Start Date Time:	Dec/9/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/9/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	NO

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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	[]

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Grade 3 Headache]
4.	Start Date Time:	Dec/9/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/9/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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	[]

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[Back to Form](#)

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	[]

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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Concomitant Medications

1.	What is the medication identifier?	[]
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?	

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/10/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/10/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Dec/10/2020 Contact Outcome: VISIT ARRANGED
3.	Comments:	[]

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/10/2020

Form: VITAL SIGNS - TEMP

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Dec/10/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessment Of Local Reaction

1.	Date of Assessment:	Dec/10/2020
2.	Injection Site Location	DELTOID MUSCLE
3.	Injection Site Body Side:	LEFT

Reaction

4.a	Reaction:	REDNESS
	Reaction Present:	NO
4.b	Reaction:	SWELLING
	Reaction Present:	NO

Symptom

5.a	Symptom:	PAIN AT INJECTION SITE
	Symptom Present:	YES Symptom Grade: 3 Event related to Study Treatment? YES
5.b	Symptom:	FATIGUE/TIREDNESS
	Symptom Present:	YES Symptom Grade: 3 Event related to Study Treatment? YES

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

5.c	Symptom:	HEADACHE
	Symptom Present:	YES Symptom Grade: 3 Event related to Study Treatment? YES
5.d	Symptom:	VOMITING
	Symptom Present:	NO
5.e	Symptom:	DIARRHEA
	Symptom Present:	NO
5.f	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Symptom Present:	YES Symptom Grade: 1 Event related to Study Treatment? YES
5.g	Symptom:	NEW OR WORSENERED JOINT PAIN
	Symptom Present:	NO
5.h	Symptom:	CHILLS
	Symptom Present:	YES Symptom Grade: 1 Event related to Study Treatment? YES

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Vaccination

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

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Dec/9/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
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: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	
----	---	--

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Treatment Unblinded

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Dec/9/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Charles Harper	Approved	Feb-24-2021 00:30:07 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-09-2020 08:44:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Second vaccination withheld due to subject having severe reactions to first vaccination
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Second vaccination withheld due to subject having severe reactions to first vaccination
			Not Done

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
2	Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Second vaccination withheld due to subject having severe reactions to first vaccination
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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Item	Date	User	Comment
3	Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done
3	Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
3	Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Second vaccination withheld due to subject having severe reactions to first vaccination <hr/> Not Done

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
4	Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Second vaccination withheld due to subject having severe reactions to first vaccination
			Not Done

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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Item	Date	User	Comment
5	Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done
5	Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	
5	Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Second vaccination withheld due to subject having severe reactions to first vaccination
			Not Done

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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Item	Date	User	Comment
6	Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
6	Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
6	Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Second vaccination withheld due to subject having severe reactions to first vaccination
			Not Done

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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Item	Date	User	Comment
7	Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
7	Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
7	Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Second vaccination withheld due to subject having severe reactions to first vaccination
			Not Done

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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Item	Date	User	Comment
8	Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
8	Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
8	Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Second vaccination withheld due to subject having severe reactions to first vaccination
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
9	Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done
9	Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	
9	Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Second vaccination withheld due to subject having severe reactions to first vaccination
			Not Done

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
10	Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
10	Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
10	Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Second vaccination withheld due to subject having severe reactions to first vaccination
			Not Done

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
11	Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
11	Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
11	Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Second vaccination withheld due to subject having severe reactions to first vaccination
			Not Done

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.b	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.c	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.d	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.e	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2 f	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.g	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2 h	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.a	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.c	Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Charles Harper	Approved	Feb-24-2021 00:30:07 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Feb-17-2021 15:36:43 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Charles Harper	Approved	Feb-09-2021 22:52:34 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Jan-29-2021 15:42:14 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Charles Harper	Approved	Jan-09-2021 11:28:32 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Dec-31-2020 09:48:27 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Charles Harper	Approved	Dec-30-2020 23:18:43 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Dec-30-2020 14:59:58 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Charles Harper	Approved	Dec-14-2020 22:48:40 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

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

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

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

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Dec-09-2020 08:43:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 06 OCT 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Dec-09-2020 08:43:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Dec-09-2020 08:44:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Dec/8/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Dec-09-2020 08:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11251243	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Dec-09-2020 08:41:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 2003	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Dec-09-2020 08:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Dec-09-2020 08:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Dec-09-2020 08:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-09-2020 08:44:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/8/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Dec-09-2020 08:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-09-2020 08:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-09-2020 08:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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1.a

Date	Location	User	Value	Reason
Dec-09-2020 08:48:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T Seasonal aller erm: gies Start Date: UNK/UNK/2 004 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Dec-09-2020 08:48:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Dec-09-2020 08:48:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Seasonal allergies	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Dec-09-2020 08:48:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2004	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Dec-09-2020 08:48:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

I.b

Date	Location	User	Value	Reason
Dec-09-2020 08:49:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Tonsillitis Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

I.b Line/MH Number:

Date	Location	User	Value	Reason
Dec-09-2020 08:49:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

I.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Dec-09-2020 08:49:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tonsillitis	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Dec-09-2020 08:49:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Dec-09-2020 08:49:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

I.c

Date	Location	User	Value	Reason
Dec-09-2020 08:50:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Tonsillectomy Start Date: UNK/UNK/2005	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

			Ongoing:	NO End Date: UNK/UNK/ 2005
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Dec-09-2020 08:50:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Dec-09-2020 08:50:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Tonsillectomy	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Dec-09-2020 08:50:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2005	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Dec-09-2020 08:50:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Dec-09-2020 08:47:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Dec-09-2020 08:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/8/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Dec-09-2020 08:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 132.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Dec-09-2020 08:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Dec-09-2020 08:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 65.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Dec-09-2020 08:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Dec-09-2020 08:51:48 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22.0	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Time (US & Canada)				
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7.a

Date	Location	User	Value	Reason
Dec-09-2020 08:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 98.2 Temperature Unit F : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Dec-09-2020 08:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Dec-09-2020 08:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Dec-09-2020 08:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Dec-09-2020 08:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Dec-09-2020 08:52:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/8/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Dec-09-2020 08:52:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 112420	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Dec-09-2020 08:52:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-09-2020 08:52:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-09-2020 17:04:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-09-2020 08:52:43 (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-09-2020 08:52:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-09-2020 17:04:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7CHW	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-09-2020 17:04:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7CHW	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-09-2020 17:05:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR7CHX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-09-2020 17:05:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7CHX	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-09-2020 17:05:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMPGMT	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-09-2020 17:05:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMPGMT	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-09-2020 17:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS5H14	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Dec-09-2020 17:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS5H14	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1125**Site Name:** (1125) Meridian Clinical Research**Subject No:** 11251243**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-09-2020 08:53:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-09-2020 08:53:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-09-2020 17:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-09-2020 08:53:12 (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-09-2020 08:53:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-09-2020 17:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPTN04	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-09-2020 17:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPTN04	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-09-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-09-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-09-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-14-2020 00:52:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Unplanned visit added
Dec-11-2020 16:57:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	eCRF added
Dec-11-2020 00:09:24 (UTC-06:00) Central Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Subject has reported with Severe symptoms

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

(US & Canada)				reactions on 2020 12 09 . Per protocol, subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form as appropriate. (b) (4)
Dec-09-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/8/20 20 18:03	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-09-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-09-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Dec-09-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-09-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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
Dec-09-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Dec-09-2020 08:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-30-2020 14:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/30/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the last O day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

			GU E Were fever or systemic sy NO mptoms present on the las t day the Subject Diary wa s completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-30-2020 15:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Dec-30-2020 15:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/30/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-30-2020 15:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 98.4 Temperature Unit F : Temperature Location: ORAL CAV ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-30-2020 15:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Dec-30-2020 15:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Dec-30-2020 15:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Dec-30-2020 15:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Dec-30-2020 15:02:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-30-2020 15:02:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-31-2020 09:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-30-2020 23:00:31 (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-30-2020 15:02:30 (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-30-2020 15:02:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/30/2020	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Dec-31-2020 09:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPTN0Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-31-2020 09:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPTN0Y	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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I. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-23-2021 10:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Feb-22-2021 18:10:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-05-2021 14:37:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Reissued:Opened	CLINQUERY: If second dose will not be given (not just delayed), please capture events in AE listing since related to end of treatment. EOT page then also needs updating to match date and reason for Rx discontinuation
Feb-05-2021 09:21:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Second dose was withheld due to subject reporting severe side effects to first vaccine, including headache and injection site pain.
Feb-05-2021 06:29:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Please clarify why second dose of study vax was not

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Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1125**Subject No:** 11251243**Generated By:** (b) (4)**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1125) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:09

				given. There is no AE or other data in CRF. EOT status should match to the reason why treatment was discontinued.
Jan-04-2021 02:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as per site response.
Dec-31-2020 09:49:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per PI patient to not receive 2nd vaccine
Dec-31-2020 04:19:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please confirm if Comment entered needs to be recorded in appropriate data point. Please confirm and correct else clarify, thank you.
Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-22-2021 18:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 18:08:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-30-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-02-2021 04:05:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-01-2021 09:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-01-2021 03:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete EOT visit. Thank you.
Jan-29-2021 15:42:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-23-2021 01:30:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site.
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 08:21:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-22-2021 08:21:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-09-2021 06:53:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Vaccination 2 is 'Not Done' and eDiary data not available however corresponding 'Symptom Resolved CRF' in visit 3 is entered with data. Kindly verify and consider updating form level comment as Not Applicable. Thanks!
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

			VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Not Do ne	
Feb-22-2021 08:21:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom::	FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom::	FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?:

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 08:21:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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2.b

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?: Not Do ne	Initial Entry
Feb-22-2021 08:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 08:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic s Not ymptoms present on the Don last day the Subject Diar e y was completed?:	Initial Entry
Feb-22-2021 08:22:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Transcription Error

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE NO Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 08:22:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH ILL	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

			<p>S</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Done</p>	
Feb-22-2021 08:22:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: CH IL LS</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p>	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: CH IL LS</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO</p>	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

2.d Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Feb-22-2021 08:22:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic s ymptoms present on the last day the Subject Diar e y was completed?:	Initial Entry
Feb-22-2021 08:23:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic s ymptoms present on the last day the Subject Diar y was completed?:	Transcription Error

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic s ymptoms present on the last day the Subject Diar y was completed?: NO	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 08:23:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic s ymptoms present on the I Don ast day the Subject Diary e was completed?:	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Feb-22-2021 08:23:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic s ymptoms present on the l ast day the Subject Diary was completed?:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 08:23:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste mic symptoms pres ent on the last day t he Subject Diary w as completed?: Not Done	Initial Entry
Feb-22-2021 08:23:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste mic symptoms pres ent on the last day t he Subject Diary w as completed?:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste mic symptoms pres ent on the last day t he Subject Diary w as completed?: NO	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 08:23:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NEW OR WORSE NEW OR WORSE NEW OR WORSE Were fever or system Not Done ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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2.h				
Date	Location	User	Value	Reason
Feb-22-2021 08:23:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WORS ENED J OINT PA IN Were fever or syste mic symptoms prese nt on the last day th e Subject Diary was completed?:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WORS ENED J OINT PA IN Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 08:23:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Feb-22-2021 08:21:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Feb-22-2021 08:23:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: Not Don	Initial Entry
Feb-22-2021 08:23:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 15:45:32 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4), (b) (6)
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 08:23:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site react Not ions present on the last Don day the Subject Diary w e as completed?:	Initial Entry
Feb-22-2021 08:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site react ions present on the last day the Subject Diary w as completed?:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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Subject Initials: ---

Generated By: (b) (4)

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

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Feb-22-2021 08:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry
Feb-22-2021 08:24:18 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)		(b) (4), (b) (6)	Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Feb-22-2021 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-22-2021 08:24:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-29-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-29-2021 15:45:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-29-2021 15:45:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-01-2021 15:00:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-31-2021 21:09:43 (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.
Jan-29-2021 15:45:48 (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.
Jan-29-2021 15:45:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/29/2021	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Feb-01-2021 15:00:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPTN6T	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 15:00:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPTN6T	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-01-2021 15:00:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPTN6V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 15:00:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPTN6V	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-01-2021 15:00:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMPGRC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 15:00:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMPGRC	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

5.d

Date	Location	User	Value	Reason
Feb-01-2021 15:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS5H3K	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 15:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS5H3K	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-22-2021 17:43:40 (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: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Grade 3 Pain at Injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/9/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/9/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	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-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-22-2021 17:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Grade 3 Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/9/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/9/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	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-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-22-2021 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-11-2020 16:17:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/10/2020	Transcription Error
Dec-11-2020 16:17:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/11/2020	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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I. Assessments

Date	Location	User	Value	Reason
Dec-11-2020 16:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-11-2020 16:17:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Dec-11-2020 16:17:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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1. Contact Type:

Date	Location	User	Value	Reason
Dec-11-2020 16:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Dec-11-2020 16:31:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-11-2020 16:17:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-11-2020 16:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Dec-11-2020 16:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Contact 10/Dec/2020 is not equal to the Date of Visit 11/Dec/2020 within same unplanned visit. Please review and update as appropriate.
Dec-11-2020 16:17:40	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form Version: 22-Apr-2020 21:04

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

(UTC-06:00) Central Time (US & Canada)

(b) (4), (b) (6)

YES

Date of Contact:

Dec/10/2020

Contact Outcome:

VISIT ARRANGED

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Dec/10/2020**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1125**Site Name:** (1125) Meridian Clinical Research**Subject No:** 11251243**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Dec-11-2020 16:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-11-2020 16:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 98.0 Temperature Unit F : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-11-2020 16:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Dec-11-2020 16:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Dec-11-2020 16:18:31 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)

(b) (4), (b) (6)

2.a Temperature Location:

Date	Location	User	Value	Reason
Dec-11-2020 16:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Dec/10/2020**Form Version:** 10-Dec-2020 02:22**Site No:** 1125**Subject No:** 11251243**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1125) Meridian Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-11-2020 16:31:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/10/2020	Initial Entry

2. Injection Site Location

Date	Location	User	Value	Reason
Dec-11-2020 16:31:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-11-2020 16:31:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

4.a

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: REDNESS Reaction Present:: NO	Initial Entry

4.a Reaction:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

4.a Reaction Present:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form Version: 10-Dec-2020 02:22

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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4.b

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: SWELLING Reaction Present:: NO	Initial Entry

4.b Reaction:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: PAIN AT INJECTIO : N SITE Symptom YES Present:: Symptom Grade: 3 Event related to St udy Treatment? YES	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

5.a Symptom:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Symptom Grade: 3 Event related to Study Treatment? YES	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: FATIGUE/TIREDNESS : ESS Symptom Present: YES Symptom Grade: 3 Event related to Study Treatment? YES	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form Version: 10-Dec-2020 02:22

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

5.b Symptom:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE/TIREDNESS	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Symptom Grade: 3 Event related to Study Treatment? YES	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: HEADACHE : Symptom Present:: YES Symptom Grade: 3 Event related to Study Treatment? YES	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

5.c Symptom:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Symptom Grade: 3 Event related to Study Treatment ? YES	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VOMITIN G Symptom Present: NO :	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

5.d Symptom:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIARRHEA A Symptom Present: NO :	Initial Entry

5.e Symptom:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.f

Date	Location	User	Value	Reason
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090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form Version: 10-Dec-2020 02:22

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR WORSE :: ED MUSCLE PAIN Symptom YES Present:: Symptom Grade: 1 Event related to Stu dy Treatment? YES	Initial Entry
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5.f Symptom:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCL E PAIN	Initial Entry

5.f Symptom Present:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Symptom Grade: 1 Event related to Study Treatment ? YES	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR WORSE : NED JOINT PAIN Symptom NO Present::	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form Version: 10-Dec-2020 02:22

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

5.g Symptom:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT P AIN	Initial Entry

5.g Symptom Present:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.h

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: CHILLS : Symptom YES Present:: Symptom Grade: 1 Event related to St udy Treatment? YES	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/10/2020

Form Version: 10-Dec-2020 02:22

Site No: 1125

Subject No: 11251243

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1125) Meridian Clinical Research

Subject Initials: ---

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

5.h Symptom:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

5.h Symptom Present:

Date	Location	User	Value	Reason
Dec-11-2020 16:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Symptom Grade: 1 Event related to Study Treatment ? YES	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1125**Site Name:** (1125) Meridian Clinical Research**Subject No:** 11251243**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)***1. Date of Completion/Discontinuation/Death :***

Date	Location	User	Value	Reason
Feb-22-2021 18:09:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-22-2021 18:09:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/9/2020	Transcription Error
Feb-22-2021 18:09:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Completion/Discontinuation /Death" 09/Dec/2021 is a future date relative to when it was entered on 22/feb /2021. Please correct.
Feb-22-2021 18:09:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/9/2021	Transcription Error
Feb-22-2021 18:08:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Completion/Discontinuation /Death" 29/Dec/2021 is a future date relative to when it was entered on 22/feb /2021. Please correct.
Feb-22-2021 18:08:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/29/2021	New Information
Feb-01-2021 09:32:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/29/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-01-2021 09:32:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

3. Status:

Date	Location	User	Value	Reason
Feb-23-2021 11:00:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Closed	Response satisfies query
Feb-23-2021 10:09:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Per query
Feb-23-2021 10:09:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : ADVERSE EVENT	Per query
Feb-23-2021 05:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Opened	CLINQUERY: AEs are listed reporting DRUG WITHDRAWN in response to the events. If correct, please amend status selection on this end of treatment page to be ADVERSE EVENT to match to the AE entries
Feb-22-2021 18:09:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-22-2021 18:09:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry	New Information

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)			PHYSICIAN DECISION	
Feb-17-2021 20:53:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_23
Feb-17-2021 15:36:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is OTHER but "Specify Status" is missing.
Feb-17-2021 15:36:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-17-2021 15:36:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry OTHER	Transcription Error
Feb-03-2021 03:00:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Please update Status as per your response 'subject had second vaccination withheld'. Kindly reach out to CRA if assistance is required.
Feb-02-2021 17:36:13 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject had second vaccination withheld

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
Feb-02-2021 05:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7086116;Status on the Disposition - Treatment form is COMPLETED but at least one Dose Date is missing. Please review and update as appropriate.
Feb-01-2021 09:32:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : COM PLET ED	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject Status

Date	Location	User	Value	Reason
Feb-23-2021 10:09:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Per query
Feb-22-2021 18:09:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	New Information
Feb-17-2021 15:36:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Transcription Error
Feb-01-2021 09:32:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Dec-09-2020 08:52:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Dec-09-2020 08:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Feb-23-2021 10:09:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/9/2020	Per query
Feb-22-2021 18:09:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/9/2020	New Information
Feb-22-2021 18:09:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/9/2020	Transcription Error
Feb-22-2021 18:09:00 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/9/2021	Transcription Error

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
Feb-22-2021 18:08:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/29/2021	New Information
Feb-17-2021 15:36:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/29/2021	Transcription Error
Feb-01-2021 09:32:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/29/2021	Initial Entry
Dec-09-2020 08:52:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/8/2020	Initial Entry
Dec-09-2020 08:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/8/2020	Initial Entry

090177e196ae3d1f\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1125

Site Name: (1125) Meridian Clinical Research

Subject No: 11251243

Subject Initials: ---

Generated By: (b) (4)

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Dec-10-2020 17:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry