

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/13/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11711023]
2.	Birth Date:	(b) (6)/1973
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/13/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Form Comments

Inclusion Criteria Not Met

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

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

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/13/2020
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: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hernia Repair]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2012
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left Foot Toe Surgery]
	Start Date:	UNK/UNK/2000
	Ongoing:	NO End Date: UNK/UNK/2000
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroidism]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Testicular Cancer]
	Start Date:	Feb/UNK/1998
	Ongoing:	NO End Date: Aug/UNK/1998

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Orchiectomy]
	Start Date:	Mar/UNK/1998
	Ongoing:	NO End Date: Mar/UNK/1998
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chemotherapy]
	Start Date:	Apr/UNK/1998
	Ongoing:	NO End Date: Apr/UNK/1998
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Meniscus Tear]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Laparoscopic Surgery]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Modified Krumplit Dissection]
	Start Date:	Aug/UNK/1998
	Ongoing:	NO End Date: Aug/UNK/1998
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergies]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/14/2020
2.	Weight:	[220.0]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[29.8]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/14/2020
2.	Randomization Number:	[50045]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP0YSX]
5.b	Sample ID	[BP0YSY]
5.c	Sample ID	[BP0YSZ]
5.d	Sample ID	[BPHHBP]
5.e	Sample ID	[BPHHBR]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP0Z3B]
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090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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:	Aug/14/2020 09:40
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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD 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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/2/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/2/2020
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	[BP0Z8X]
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090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/2/2020 09:24
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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD 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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/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	[BP9H1K]
5.b	Sample ID	[BP9H1L]
5.c	Sample ID	[BP9H1M]
5.d	Sample ID	[BRTT90]
5.e	Sample ID	[BRTT91]

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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:	[]
----	------------------------	-----

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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	[]
----	-----------	-----

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Unplanned Assessments

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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Sep/30/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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	[]
----	-----------	-----

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Urticaria on forehead, posterior neck, bilateral posterior hands and bilateral plantar areas	Feb/10/2021 12:00	NO End Date Time: Feb/16/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Angioedema - Forehead	Feb/11/2021 12:00	NO End Date Time: Feb/16/2021 UNK:UNK	Repeating Pages

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Urticaria on forehead, posterior neck, bilateral posterior hands and bilateral plantar areas]
4.	Start Date Time:	Feb/10/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/16/2021 UNK:UNK
6.	Toxicity Grade:	2
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?	YES

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Angioedema - Forehead]
4.	Start Date Time:	Feb/11/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/16/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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	[]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Medication Error

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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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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:	//

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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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?	

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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?	

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1 2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/4/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/9/2021
----	--------------	---

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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
----	--	----------------

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Feb/9/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/9/2021
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	[BR2Z94]
5.b	Sample ID	[BR2Z95]
5.c	Sample ID	[BR2Z96]
5.d	Sample ID	[BLG59L]
5.e	Sample ID	[BLG59M]

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/9/2021
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	[BR2Z93]
-----	-----------	----------

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/9/2021 11:25
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Not Done _____ //	Comments
2.	Erroneous Visit	ERRONEOUS VISIT	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Mar/9/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/30/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	-------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-14-2020 09:51:58 (UTC-06:00) Central Time (US & Canada)	Mueed Bari (b) (4)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-12-2021 14:34:14 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
1	Mar-09-2021 16:15:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Per Investigator, Drug withdrawn due to AE. Visit 102 Not Done as of right now. CRA was notified about this and pending clarification on what to do next. <hr/> Not Done

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-10-2021 09:54:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
1	Mar-10-2021 09:54:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
2	Mar-10-2021 09:54:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
3	Mar-10-2021 09:54:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
4	Mar-10-2021 09:54:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
1	Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Mar-09-2021 16:16:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Visit not done. Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
2	Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
3	Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
4	Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
4	Mar-09-2021 16:17:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Visit not done. Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
5	Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
6	Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
6	Mar-09-2021 16:17:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Visit not done. Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
7	Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
8	Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
9	Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
10	Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
11	Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
11	Mar-09-2021 16:18:14 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Visit not done. 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, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-08-2021 15:33:44 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Earl Martin	Approved	Mar-03-2021 10:55:26 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
-------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, EarlMartin, 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-08-2021 10:48:24 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Earl Martin	Approved	Oct-06-2020 16:53:09 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
-------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, EarlMartin, 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.

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Mueed Bari	N/A	Sep-18-2020 10:22:19 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Earl Martin	Approved	Sep-14-2020 10:25:46 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
-------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, EarlMartin, 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.

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-14-2020 09:49:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 09:49:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> STAGE 3 COHORTS	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-14-2020 09:49:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Aug/13/2020	Transcription Error
Aug-14-2020 09:49:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: OBTAINED Date Written Consent Obtained Aug/14/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Subject ID

Date	Location	User	Value	Reason
Aug-14-2020 09:49:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 11711023	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-14-2020 09:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6)/1973	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-14-2020 09:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-14-2020 09:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 09:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-19-2020 15:27:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-19-2020 10:43:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Query 1: Answered	Original value is correct
Aug-19-2020 10:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD_Clin: Date of Visit is 13AUG2020. However, Vaccine was given 14AUG2020 when the dates should match. Please reconcile DATES and update the CRF as appropriate.
Aug-14-2020 09:51:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Aug/13/2020	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-12-2020 00:01:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Date of Completion/Discontinuation /Death updated to 13/Aug /2020.
Sep-11-2020 23:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-11-2020 23:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/13/2020	Transcription Error
Sep-11-2020 22:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Opened	*DM: Please confirm date as DOV was on 13/Aug, please correct if necessary. Thank you.
Aug-14-2020 09:52:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Aug/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-14-2020 09:52:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-14-2020 09:52:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1.a

Date	Location	User	Value	Reason
Aug-14-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Hernia Repair Term: Start Date: UNK/UNK/2012 Ongoing: NO End Date: UNK/UNK/ 2012	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 09:59:42 (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
Aug-14-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Hernia Repair	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: UNK/UNK/2012	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
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090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Aug-14-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: NO End Date: UNK/UNK/2012	Initial Entry
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I.b

Date	Location	User	Value	Reason
Aug-14-2020 10:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Left Foot Toe Surgery Start Date: UNK/UNK/2000 Ongoing: NO End Date: UNK/UNK/2000	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 10:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 10:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Left Foot Toe Surgery	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 10:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: UNK/UNK/2000	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 10:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: NO End Date: UNK/UNK/2000	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-14-2020 10:32:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3 : Medical History T Hypothyroidi erm: sm Start Date: UNK/UNK/2 000 Ongoing: YES	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 10:32:34 (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
Aug-14-2020 10:32:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Hypothyroidism	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 10:32:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: UNK/UNK/2000	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 10:32:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-14-2020 10:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Testicular Cancer Start Date: Feb/UNK/1998 Ongoing: NO End Date: Aug/UNK/1998	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 10:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 10:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Testicular Cancer	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 10:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Feb/UNK/1998	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 10:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: NO End Date: Aug/UNK/1998	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-14-2020 10:33:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Orchiectomy Start Date: Mar/UNK/1998	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

			Ongoing:	NO End Date: Mar/UNK/1998	
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I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 10:33:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 10:33:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> Orchiectomy	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 10:33:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> Mar/UNK/1998	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 10:33:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> NO End Date: Mar/UNK/1998	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-14-2020 11:56:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> Line/MH Number: 6	Transcription Error

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

			Medical History Term: Chemotherapy Start Date: Apr/UNK/1998 Ongoing: NO End Date: Apr/UNK/1998	
Aug-14-2020 10:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: N 6 Medical History Term: Chemotherapy for Testicular Cancer Start Date: Apr/UNK/1998 Ongoing: NO End Date: Apr/UNK/1998	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 10:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 13:01:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-14-2020 11:56:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-14-2020 11:56:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Chemotherapy	Transcription Error
Aug-14-2020 11:49:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term CHEMOTHERAPY FOR TESTICULAR CANCER. Split the term into CHEMOTHERAPY and TESTICULAR CANCER. Submit each term as a separate record. Thank you.
Aug-14-2020 10:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Chemotherapy for Testicular Canc	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

			er	
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I.f Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 10:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Apr/UNK/1998	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 10:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: NO End Date: Apr/UNK/1998	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-14-2020 11:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Meniscus Tear Start Date: UNK/UNK/2018 Ongoing: NO End Date: UNK/UNK/ 2018	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 11:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 11:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Meniscus Tear	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 11:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: UNK/UNK/2018	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 11:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-14-2020 11:29:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: Laparoscopic Surgery Start Date: UNK/UNK/2018	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

			Ongoing:	NO End Date: UNK/UNK/2018
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I.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 11:29:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 11:29:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Laparoscopic Surgery	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 11:29:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: UNK/UNK/2018	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 11:29:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry

I.i

Date	Location	User	Value	Reason
Aug-17-2020 09:18:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Line/MH Number: 9	Transcription Error (DELETED)

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

			Medical History Term: Modified Krumpolt Dissection Start Date: Aug/UNK/1998 Ongoing: NO End Date: Aug/UNK/1998	
Aug-14-2020 11:29:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Modified Krumpolt Dissection Start Date: Aug/UNK/1998 Ongoing: NO End Date: Aug/UNK/1998	Initial Entry

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 09:18:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: 9	Transcription Error (DELETED)
Aug-14-2020 11:29:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 08:47:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Date	Location	User	Value	Reason
Aug-17-2020 09:18:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry</u> : Modified Kr umplit Diss ection	Transcription Error (DELETED)
Aug-17-2020 09:18:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swered	Transcription Error
Aug-15-2020 00:27:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Op ened	Clarify MODIFIED KRUMPLIT DISSECTION as follows...Clarify KRUMPLIT. Are you reporting MODIFIED RADICAL NECK DISSECTION? MODIFIED RADICAL MASTECTOMY? Other? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate. Thank you.
Aug-14-2020 11:29:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry</u> : Modified Kr umplit Diss ection	Initial Entry

1.i Start Date:

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Aug-17-2020 09:18:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Aug/UNK/1998	Transcription Error (DELETED)
Aug-14-2020 11:29:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Aug/UNK/1998	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 09:18:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: NO End Date: Aug/UNK/1998	Transcription Error (DELETED)
Aug-14-2020 11:29:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: NO End Date: Aug/UNK/1998	Initial Entry

1.j

Date	Location	User	Value	Reason
Sep-18-2020 10:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 10 : Medical History T Seasonal Allergies erm: gies Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-18-2020 10:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 10:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Seasonal Allergies	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-18-2020 10:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: UNK/UNK/2015	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-18-2020 10:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: YES	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 30-Jul-2020 21:28**Site No:** 1171**Subject No:** 11711023**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1171) Martin Diagnostic Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Aug-17-2020 01:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation
Aug-14-2020 10:10:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Query 1: Answered	Original value is correct
Aug-14-2020 10:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital signs Date 14/Aug/2020 is not same as Date of Visit 13/Aug/2020. Please review and update as appropriate or clarify.
Aug-14-2020 10:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Aug/14/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-14-2020 10:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: 220.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-14-2020 10:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-14-2020 10:05:49	ACV0PFEINFP6000	Mueed Bari	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-06:00) Central Time (US & Canada)		(b) (4)	72.0	
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5. Unit:

Date	Location	User	Value	Reason
Aug-14-2020 10:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-14-2020 10:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 29.8	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-14-2020 10:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 97.8 Temperature Unit: F Temperature Location: FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-14-2020 10:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-14-2020 10:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> 97.8	Initial Entry

7.a Unit:

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Aug-14-2020 10:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-14-2020 10:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-14-2020 10:06:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Aug/14/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-14-2020 10:06:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: 50045	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Aug-14-2020 10:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-14-2020 10:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-14-2020 10:07:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-14-2020 10:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-14-2020 10:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: YES Date of Collection: Aug/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-14-2020 10:07:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Sample ID: BPOYSX	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 10:07:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> BP0YSX	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-14-2020 10:07:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> Sample ID: BP0YSY	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 10:07:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> BP0YSY	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-14-2020 10:07:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> Sample ID: BP0YSZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 10:07:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> BP0YSZ	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-14-2020 10:07:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> Sample ID: BPHHBP	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 10:07:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: BPHHBP	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-14-2020 10:07:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Sample ID: BPHHBR	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 10:07:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: BPHHBR	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Aug-14-2020 10:07:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-14-2020 10:07:56 (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
Aug-14-2020 10:08:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-14-2020 10:07:56 (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.
Aug-14-2020 10:07:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: YES Date of Collection: Aug/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-14-2020 10:08:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Sample ID: BP0Z3B	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 10:08:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> BP0Z3B	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-14-2020 10:11:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-14-2020 10:11:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-14-2020 10:11:16 (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
Aug-14-2020 10:11:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Aug/14/2020 09:40	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-14-2020 10:11:16 (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
Aug-14-2020 10:11:16 (UTC-06:00) Central	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: LEFT	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Aug-14-2020 10:11:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-14-2020 10:11:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED OB SERVATION 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
Aug-14-2020 10:11:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-14-2020 10:11:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	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: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-02-2020 08:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Sep/2/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1171**Site Name:** (1171) Martin Diagnostic Clinic**Subject No:** 11711023**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sym N ptoms present on the last da O y the Subject Diary was com pleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (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
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TIG	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (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
Sep-02-2020 09:56:29 (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
Sep-02-2020 09:56:29 (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 symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.c Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sym NO ptoms present on the last da y the Subject Diary was co mpleted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (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
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.f Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW OR WORSE ED MUS CLE PAI N Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was compl eted?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.h

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (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
Sep-02-2020 09:56:29 (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
Sep-02-2020 09:56:29 (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
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (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
Sep-02-2020 09:56:29 (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
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (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
Sep-02-2020 09:56:29 (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
Sep-02-2020 09:56:29 (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?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Sep-02-2020 09:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date:

Date	Location	User	Value	Reason
Sep-02-2020 09:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/2/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-02-2020 09:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Locati on:: FOREHEA D	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-02-2020 09:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-02-2020 09:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-02-2020 09:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> F	Initial Entry

2.a Temperature Location:

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Sep-02-2020 09:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Sep-02-2020 10:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-02-2020 10:30:32 (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
Sep-02-2020 10:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-02-2020 10:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-02-2020 10:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-02-2020 10:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP0Z8X	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 10:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP0Z8X	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-02-2020 09:58:14 (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
Sep-02-2020 09:58:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-02-2020 09:58:14 (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
Sep-02-2020 09:58:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/2/2020 09:24	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-02-2020 09:58:14 (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
Sep-02-2020 09:58:14 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)	(b) (4), (b) (6)
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7. Route:

Date	Location	User	Value	Reason
Sep-02-2020 09:58:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-02-2020 09:58:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-02-2020 09:58:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-30-2020 08:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mueed Bari (b) (4)	Data Entry: Sep/30/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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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
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sym N ptoms present on the last da O y the Subject Diary was com pleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (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
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TIG	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (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
Sep-30-2020 09:43:05 (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
Sep-30-2020 09:43:05 (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 symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.c Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sym NO ptoms present on the last da y the Subject Diary was co mpleted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (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
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.f Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW OR WORSE ED MUS CLE PAI N Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was compl eted?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSE NED MUS CLE 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
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.h

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (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 systemi c symptoms present o n the last day the Sub ject Diary was comple ted?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOI NT 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
Sep-30-2020 09:43:05 (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
Sep-30-2020 09:43:05 (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
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (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
Sep-30-2020 09:43:05 (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
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (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
Sep-30-2020 09:43:05 (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
Sep-30-2020 09:43:05 (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?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Sep-30-2020 09:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Sep-30-2020 10:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-30-2020 10:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-30-2020 10:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020 10:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-30-2020 10:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-30-2020 10:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP9H1K	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 10:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP9H1K	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-30-2020 10:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP9H1L	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 10:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP9H1L	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-30-2020 10:23:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP9H1M	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 10:23:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP9H1M	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-30-2020 10:23:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BR9T90	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 10:23:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRTT90	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-30-2020 10:23:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRTT91	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 10:23:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRTT91	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-02-2020 10:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/30/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-02-2020 10:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-02-2020 10:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COMPLETED	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Date	Location	User	Value	Reason
Feb-12-2021 14:30:59 (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: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Date	Location	User	Value	Reason
Feb-12-2021 14:32:57 (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: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 14:30:59 (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-12-2021 14:30:59 (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
Mar-12-2021 16:59:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-12-2021 15:55:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-12-2021 15:55:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Urticaria on forehead, posterior neck, bilateral posterior hands and bilateral plantar areas	Changed Information
Mar-10-2021 08:21:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls update AE term to indicate if generalized or specify anatomic location.
Feb-12-2021 14:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hives	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (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

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Feb-12-2021 14:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/10/2021 12:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-09-2021 14:25:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-08-2021 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-08-2021 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/16/2021 UNK:UNK	New Information
Mar-03-2021 16:21:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please verify if Hives are ongoing, then update the END DATE and OUTCOME as appropriate
Feb-12-2021 14:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-12-2021 14:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-12-2021 14:30:59 (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-12-2021 14:30:59 (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-12-2021 14:30:59 (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
Mar-10-2021 12:43:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-10-2021 09:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-10-2021 09:34:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: "Latest action taken with study treatment" on AE form is DRUG WITHDRAWN and EOT status in END_OF_TRT visit is not ADVERSE EVENT. Please consider to update the EOT2 form accordingly. Else

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

				clarify. Thank you.
Mar-09-2021 16:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Updated Per source.
Feb-12-2021 14:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-12-2021 14:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 14:30:59 (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
Mar-08-2021 15:34:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-08-2021 15:34:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Mar-08-2021 15:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Hives: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-12-2021 14:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Date	Location	User	Value	Reason
Feb-12-2021 14:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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, Queries

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 14:32:57 (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-12-2021 14:32:57 (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
Mar-09-2021 18:11:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	clinical: Thanks, was diagnosis confirmed by physician or was this by self report?
Mar-09-2021 16:06:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per source, not in Medical History for this subject. Per Investigator, Action taken to Study Treatment updated to Drug Withdrawn.
Feb-19-2021 14:39:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Feb-18-2021 16:13:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	clinical: pls confirm subject has no prior hx of angioedema. Thanks
Feb-18-2021 16:10:55 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1171**Subject No:** 11711023**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Queries**Site Name:** (1171) Martin Diagnostic Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

Time (US & Canada)				
Feb-18-2021 16:10:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-18-2021 16:10:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Angioedema - Forehead	Changed Information
Feb-18-2021 14:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	clinical: please confirm subject has no prior history of angioedema. Thanks
Feb-15-2021 13:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please provide the location/ anatomic site of angioedema in the answer.
Feb-12-2021 14:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Angioedema	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 14:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 16:12:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/16/2021 UNK:UNK	New Information
Feb-17-2021 09:39:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 15:25:05	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		correct
Feb-16-2021 08:55:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls confirm AE still ongoing or update end date in CRF. Thanks
Feb-12-2021 14:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-12-2021 14:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-12-2021 14:33:11 (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-12-2021 14:32:57 (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-12-2021 14:32:57	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	RELATED	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-09-2021 16:08:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Updated Per source.
Feb-12-2021 14:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-19-2021 14:40:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Feb-18-2021 16:11:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-18-2021 16:11:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Feb-17-2021 21:28:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Reissued:Opened	GPDClin: Thank you! Per your previous answer, please change to "Yes" here.
Feb-17-2021 17:15:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject took Benadryl 50mg orally and applied topical hydrocortisone cream 2.5% before contacting site and reported symptoms were improving. Subject was advised to seek medical attention if

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

				symptoms worsen.
Feb-15-2021 13:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify if any treatment was given.
Feb-12-2021 14:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 14:32:57 (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-18-2021 16:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 16:13:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Feb-18-2021 16:12:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Angioedema - Forehead: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-12-2021 14:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 14:32:57 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)

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

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-08-2021 10:48:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/4/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Date	Location	User	Value	Reason
Feb-08-2021 10:48:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national reco mmendations and confirmed t o have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-08-2021 10:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/4/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-08-2021 10:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-12-2021 14:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-12-2021 14:34:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: OBTAINED Date Written Consent Obtained Feb/9/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION
- eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-12-2021 14:34:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-12-2021 14:34:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-12-2021 14:34:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Feb-12-2021 14:34:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-12-2021 14:34:51 (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-12-2021 14:35:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-12-2021 14:34:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-12-2021 14:34:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-12-2021 14:35:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR2Z94	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 15:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_06
Feb-19-2021 10:19:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Changed data per query
Feb-18-2021 09:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	DM: Please update data per query response provided. Thank you.
Feb-17-2021 08:32:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Candi date	DM: Please update data per query response provided. Thank you.
Feb-16-2021 15:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Please unlock all forms in V101_VAX3 for 11711161 so changes may be made
Feb-16-2021 05:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW7250542;The barcode BR2Z94 is recorded for two subjects 11711023, and 11711161, please review and update as appropriate.

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Feb-12-2021 14:35:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : BR2Z 94	Initial Entry
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5.b

Date	Location	User	Value	Reason
Feb-12-2021 14:35:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BR2Z95	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 15:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_06
Feb-19-2021 10:19:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Changed data per query
Feb-19-2021 04:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	DM1: The requested page is unfrozen. Please have the changes done to remove the duplicate barcode BR2Z95 .
Feb-17-2021 09:59:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Candi date	Pending 11711161 update
Feb-16-2021 15:19:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Please unlock all forms in V101_VAX3 for 11711161 so changes may be made
Feb-16-2021 05:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW7250543;The barcode BR2Z95 is recorded for two subjects 11711023, and 11711161, please review and update as appropriate.

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Feb-12-2021 14:35:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry : BR2Z 95	Initial Entry
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5.c

Date	Location	User	Value	Reason
Feb-12-2021 14:35:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID: BR2Z96	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.c Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 15:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_06
Feb-19-2021 10:19:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Changed data per query
Feb-18-2021 09:08:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	DM: Please update data per query response provided. Thank you.
Feb-17-2021 08:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Candi date	DM: Please update data per query response provided. Thank you.
Feb-16-2021 15:18:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Please unlock all forms in v101_VAX3 for subject 11711161 so changes may be made
Feb-16-2021 05:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW7250544;The barcode BR2Z96 is recorded for two subjects 11711023, and 11711161, please review and update as appropriate.

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Feb-12-2021 14:35:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : BR2Z 96	Initial Entry
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5.d

Date	Location	User	Value	Reason
Feb-12-2021 14:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BLG59L	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 15:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_06
Feb-19-2021 10:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Changed data per query
Feb-17-2021 00:00:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	DM : For subject 11711161 : ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY in V101XAX3 is unfrozen now. Please review and update the data per previous query. Thank you.
Feb-16-2021 15:18:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Please unlock all forms in V101_VAX3 for 11711161 so changes may be made
Feb-16-2021 05:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7250540;The barcode BLG59L is recorded for two subjects 11711023, and 11711161, please review and update as appropriate.
Feb-12-2021 14:35:21	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

BLG5
9L

5.e

Date	Location	User	Value	Reason
Feb-12-2021 14:35:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLG59M	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.e Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 15:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_06
Feb-19-2021 10:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Changed data per query
Feb-17-2021 08:31:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	DM: Please update data per query response provided. Thank you.
Feb-16-2021 15:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Please unlock all forms in V101_VAX3 for 11711161 so changes may be made
Feb-16-2021 05:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW7250541;The barcode BLG59M is recorded for two subjects 11711023, and 11711161, please review and update as appropriate.
Feb-12-2021 14:35:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : BLG5 9M	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Feb-12-2021 14:35:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-12-2021 14:35:38 (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
Feb-12-2021 14:35:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-12-2021 14:35:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-12-2021 14:35:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-12-2021 14:35:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR2Z93	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 15:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_06
Feb-19-2021 10:21:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Changed data per query
Feb-19-2021 04:19:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	DM1: The requested page is unfrozen. Please have the changes done to remove the duplicate barcode BR2Z93.
Feb-17-2021 09:59:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Candi date	Pending 1171161 update
Feb-16-2021 15:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Please unlock all forms in V101_VAX3 for 1171161 so changes may be made
Feb-16-2021 05:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW7250545;The barcode BR2Z93 is recorded for two subjects 11711023, and 1171161, please review and update as appropriate.

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Feb-12-2021 14:35:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : BR2Z 93	Initial Entry
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Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-12-2021 14:36:59 (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
Feb-12-2021 14:36:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-12-2021 14:36:59 (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
Feb-12-2021 14:36:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021 11:25	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-12-2021 14:36:59 (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
Feb-12-2021 14:36:59 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)	(b) (4), (b) (6)
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7. Route:

Date	Location	User	Value	Reason
Feb-12-2021 14:36:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-12-2021 14:36:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-12-2021 14:36:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-12-2021 14:36:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-12-2021 14:36:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 00:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Closed	Response satisfies query
Mar-11-2021 12:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-11-2021 05:44:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thank you for reply. However, Form level comment is still missing on VACIN TRT form. Kindly erase all item level comments and then add form level comment by selecting Not Done or Not Applicable radio button option on VACIN TRT form or else clarify.
Mar-10-2021 09:54:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-10-2021 00:15:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: DOV marked as Not Done. However, form level comment is not present on rest of forms. Kindly erase all the data and item level comments on rest of forms and then add form level comment by selecting Not Done

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

				or Not Applicable option on rest of forms.
Mar-09-2021 16:15:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-10-2021 09:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Mar-10-2021 09:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Mar-10-2021 09:53:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-09-2021 16:15:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-10-2021 09:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Mar-10-2021 09:53:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Mar-09-2021 16:15:54 (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
Mar-10-2021 09:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Mar-10-2021 09:53:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-10-2021 09:53:53 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)		(b) (4), (b) (6)		
Mar-10-2021 09:53:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Mar-09-2021 16:15:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Mar-10-2021 09:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Mar-10-2021 09:53:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Mar-09-2021 16:15:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Visit Not Done.	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-12-2021 00:08:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Closed	Response satisfies query
Mar-11-2021 12:31:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Mar-10-2021 23:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Opened	P21 Review - If no vaccination given, please provide form level comment as Not Done. Else clarify.
Mar-09-2021 16:16:25 (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
Mar-11-2021 11:38:41 (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
Mar-11-2021 11:38:41 (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
Mar-09-2021 16:17:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-11-2021 11:38:41 (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
Mar-09-2021 16:17:58 (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
Mar-11-2021 11:38:41 (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
Mar-11-2021 11:38:41 (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
Mar-11-2021 11:38:41 (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
Mar-11-2021 11:38:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

II. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Mar-09-2021 16:18:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-10-2021 09:44:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/9/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-10-2021 09:44:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-10-2021 09:44:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ADVERSE EVENT	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Subject Status

Date	Location	User	Value	Reason
Mar-10-2021 02:57:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	It will be tracked per site response.
Mar-09-2021 16:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please see comment for Visit 102 Visit Date CRF. Awaiting clarification from Study Monitor on what to do next for this subject.
Mar-09-2021 00:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM:Visit V102 overdue based on expected visit window.Please enter data or, if visit will never occur,Mark Date of Visit as Not Done with form level comment. If subject is no longer in the trial,complete the Disposition FUP form & Disposition- Treatment(EOT
Oct-02-2020 10:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-14-2020 10:06:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-14-2020 09:52:22 (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
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090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711023

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Oct-02-2020 10:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/30/2020	Initial Entry
Sep-11-2020 23:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/14/2020	Transcription Error
Aug-14-2020 10:06:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/14/2020	Initial Entry
Aug-14-2020 09:52:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/14/2020	Initial Entry

090177e196ae3d4a\Final\Final On: 01-Apr-2021 04:29 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711023

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Casebook Signature

Date	Location	User	Value	Reason
Sep-14-2020 10:21:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry