

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

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/20/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11571066]
2.	Birth Date:	(b) (6) /1956
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: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/20/2020
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: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

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:	[Hypertension]
	Start Date:	UNK/UNK/1994
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Artery Disease]
	Start Date:	UNK/UNK/1994
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
	Start Date:	UNK/UNK/1994
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Artery Stent Placement]
	Start Date:	UNK/UNK/1994
	Ongoing:	NO End Date: UNK/UNK/1994

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Artery Stent Placement]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vasectomy]
	Start Date:	UNK/UNK/1985
	Ongoing:	NO End Date: UNK/UNK/1985

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/20/2020
2.	Weight:	[284.0]
3.	Unit:	LB
4.	Height:	[71.0]
5.	Unit:	in
6.	Body Mass Index:	[39.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/20/2020
2.	Randomization Number:	[235770]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

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/20/2020
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	[BPHRFF]
5.b	Sample ID	[BPHRFG]
5.c	Sample ID	[BPHRFH]
5.d	Sample ID	[BPHRFJ]
5.e	Sample ID	[BP16Y7]
5.f	Sample ID	[BP16Y8]
5.g	Sample ID	[BP16Y9]

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

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/20/2020
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	[BP16WZ]
-----	-----------	----------

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

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/20/2020 16:06
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

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001	Form: REACTOGENICITY DIARY
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 06-Jul-2020 21:53	Site Name: (1157) Paradigm Research
Site No: 1157	Subject Initials: ---
Subject No: 11571066	Generated Time (GMT): 29-Mar-2021 12:23
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/9/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

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/9/2020
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	[BP1WMT]
-----	-----------	----------

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

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/9/2020 17:27
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

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

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: Oct/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1704]
5.b	Sample ID	[BP1705]
5.c	Sample ID	[BP1706]
5.d	Sample ID	[BPN4K0]
5.e	Sample ID	[BPN4K1]

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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?	
----	--	--

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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 :	Oct/14/2020
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: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1157) Paradigm Research

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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	Hematuria	Sep/4/2020 07:00	NO End Date Time: Oct/14/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Lymphadenopathy left side of neck	Sep/3/2020 UNK:UNK	NO End Date Time: Sep/13/2020 UNK:UNK	Repeating Pages

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)
[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)	[Hematuria]
4.	Start Date Time:	Sep/4/2020 07:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/14/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown, subject advised to seek medical attention]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

11.	Was a Concomitant Medication given?	NO
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	[]

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Lymphadenopathy left side of neck]
4.	Start Date Time:	Sep/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/13/2020 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:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1157) Paradigm Research

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	[]

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

Medication Error

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

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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 Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Status: Not Started

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

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:	//

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

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?	

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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?	

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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	Jan/27/2021
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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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 and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/27/2021
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: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1157) Paradigm Research

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 Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1157) Paradigm Research

Subject Initials: ---

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: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/14/2020

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-22-2020 09:57:24 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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	Feb-08-2021 08:29:32 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Jamshid Saleh	Approved	Oct-21-2020 16:01:55 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, JamshidSaleh, 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.

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

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-22-2020 09:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 09:56:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-22-2020 09:56:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/20/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-22-2020 09:56:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11571066	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-22-2020 09:56:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1956	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-22-2020 09:57:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-22-2020 09:57:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 09:57:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Aug-22-2020 09:57:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-22-2020 09:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-22-2020 09:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-22-2020 09:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Aug-22-2020 09:58:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Hypertension Start Date: UNK/UNK/1994 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:58:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 09:58:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-22-2020 09:58:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1994	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-22-2020 09:58:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-22-2020 09:58:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbr 2 er: Medical History Coronary Artery Term: Disease Start Date: UNK/UNK/1994 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:58:19 (UTC-08:00) Pacific 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-22-2020 09:58:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Coronary Artery Disease	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-22-2020 09:58:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1994	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-22-2020 09:58:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-22-2020 09:58:34 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

(US & Canada)			Medical History Term:	Hyperlipidemia
			Start Date:	UNK/UNK/1994
			Ongoing:	YES

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:58:34 (UTC-08:00) Pacific 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-22-2020 09:58:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hyperlipidemia	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-22-2020 09:58:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1994	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-22-2020 09:58:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-22-2020 09:58:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Coronary Artery Stent Placement	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

			Start Date: UNK/UNK/1994 Ongoing: NO End Date: UNK/UNK/1994
--	--	--	--

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:58:57 (UTC-08:00) Pacific 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-22-2020 09:58:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Coronary Artery Stent Placement	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-22-2020 09:58:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1994	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-22-2020 09:58:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1994	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-22-2020 09:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 5 mber:	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

			Medical History Term: Coronary Artery Stent Placement Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/2016	
--	--	--	--	--

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 09:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Coronary Artery Stent Placement	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-22-2020 09:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-22-2020 09:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2016	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-22-2020 09:59:47 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 6	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

(US & Canada)			r: Medical History Term: Vasectomy Start Date: UNK/UNK/1985 Ongoing: NO End Date: UNK/UNK/1985
---------------	--	--	---

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-22-2020 09:59:47 (UTC-08:00) Pacific 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-22-2020 09:59:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Vasectomy	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-22-2020 09:59:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1985	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-22-2020 09:59:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1985	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-22-2020 10:00:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-22-2020 10:00:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 284.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-22-2020 10:00:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-22-2020 10:00:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 71.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-22-2020 10:00:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-22-2020 10:00:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 39.6	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

7.a

Date	Location	User	Value	Reason
Aug-22-2020 10:00:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.3 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-22-2020 10:00:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-22-2020 10:00:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-22-2020 10:00:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-22-2020 10:00:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-22-2020 10:00:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-22-2020 10:00:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 235770	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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-22-2020 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-22-2020 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-22-2020 10:01:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-22-2020 10:00:48 (UTC-08:00) Pacific 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-22-2020 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-22-2020 10:01:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHRFF	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 10:01:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHRFF	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-22-2020 10:01:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHRFG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 10:01:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHRFG	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-22-2020 10:01:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHRFH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 10:01:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHRFH	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-22-2020 10:01:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPHRFJ	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 10:01:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPHRFJ	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-22-2020 10:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP16Y7	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 10:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP16Y7	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-22-2020 10:02:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP16Y8	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 10:02:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP16Y8	Initial Entry

5.g

Date	Location	User	Value	Reason
Aug-22-2020 10:02:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP16Y9	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 10:02:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP16Y9	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-22-2020 10:03:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-22-2020 10:03:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-22-2020 10:03:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-22-2020 10:03:09 (UTC-08:00) Pacific 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-22-2020 10:03:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-22-2020 10:03:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP16WZ	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 10:03:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP16WZ	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-22-2020 10:03:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-22-2020 10:03:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-22-2020 10:03:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-22-2020 10:03:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/20/2020 16:06	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-22-2020 10:03:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-22-2020 10:03:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Aug-22-2020 10:03:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-22-2020 10:03:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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-22-2020 10:03:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-03-2020 00:56:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-02-2020 09:26:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-02-2020 09:26:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E- DIARY COLLECTED FOR TH IS SUBJECT	Changed Information
Sep-02-2020 02:01:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'No' however VAX 1 eDiary records are available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-22-2020 10:03:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-D IARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 08:09:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific 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 co mpleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific 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-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TIG	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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?:	
--	--	--	---	--

2.b Symptom:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific 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-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific 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

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	Initial Entry
---	-----------------	---------------------	---	---------------

2.e Symptom:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE ED MUS CLE PAI N Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific 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-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT P AIN	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-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reaction NO s present on the last day th e Subject Diary was compl eted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific 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-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactio NO ns present on the last day t he Subject Diary was com pleted?:	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 08:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 08:16:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.3 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-10-2020 08:16:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 08:16:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 08:16:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 08:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 08:16:53 (UTC-08:00) Pacific 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-10-2020 08:16:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 08:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1WMT	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 08:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1WMT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 08:17:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 08:17:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-10-2020 08:17:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 06:36:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Closed	closed per site response
Sep-21-2020 02:22:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Reissu ed:Ope ned	closed per SITE response
Sep-18-2020 08:48:39 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Answ ered	There is no severe reaction documented on 9-9-2020 in this

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

(US & Canada)				subjects eDiary please review
Sep-14-2020 04:31:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1 : Opened	PDQ: Subject has reported with Severe symptoms/reactions on '2020-09-09'. Per protocol, subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form as appropriate. (b) (4)
Sep-10-2020 08:17:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020 17:27	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 08:17:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-10-2020 08:17:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

--

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-10-2020 08:17:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 08:17:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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-10-2020 08:17:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 12:35:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FE VE R Were fever or systemic sym N ptoms present on the last da O y the Subject Diary was co mpleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FA TIG	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

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?:	
--	--	--	---	--

2.b Symptom:

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific 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
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific 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

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	Initial Entry
---	-----------------	---------------------	---	---------------

2.e Symptom:

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MUS CLE PAI N Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific 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
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT P AIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reaction NO s present on the last day th e Subject Diary was compl eted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific 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
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactio NO ns present on the last day t he Subject Diary was com pleted?:	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 12:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-15-2020 12:35:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-15-2020 12:35:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-15-2020 12:36:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 12:35:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 12:35:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 12:36:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1704	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 12:36:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1704	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-15-2020 12:36:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1705	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 12:36:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1705	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 12:36:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1706	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 12:36:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1706	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-15-2020 12:36:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPN4K0	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 12:36:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPN4K0	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-15-2020 12:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPN4K1	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 12:36:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPN4K1	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-15-2020 12:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-15-2020 12:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-15-2020 12:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-10-2021 15:05:55 (UTC-08:00) Pacific 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: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-10-2021 15:07:24 (UTC-08:00) Pacific 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: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-10-2021 15:05:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-10-2021 15:05:55 (UTC-08:00) Pacific 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-10-2021 15:05:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematuria	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-10-2021 15:05:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020 07:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-10-2021 15:05:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/14/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

Mar-10-2021 15:05:55 (UTC-08:00) Pacific 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
Mar-10-2021 15:05:55 (UTC-08:00) Pacific 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
Mar-10-2021 15:05:55 (UTC-08:00) Pacific 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
Mar-10-2021 15:05:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown, subject advised to seek medical attention	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-10-2021 15:05:55	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

(UTC-08:00) Pacific Time (US & Canada)		(b) (4), (b) (6)	NOT APPLICABLE	
--	--	------------------	----------------	--

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-10-2021 15:05:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-10-2021 15:05:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 15:05:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 15:05:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-10-2021 15:07:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-10-2021 15:07:24 (UTC-08:00) Pacific 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-10-2021 15:07:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphadenopathy left side of neck	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-10-2021 15:07:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-10-2021 15:07:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

Mar-10-2021 15:07:24 (UTC-08:00) Pacific 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 require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-10-2021 15:07:24 (UTC-08:00) Pacific 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
Mar-10-2021 15:07:24 (UTC-08:00) Pacific 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
Mar-10-2021 15:07:24 (UTC-08:00) Pacific 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 15:07:24 (UTC-08:00) Pacific 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
Mar-10-2021 15:07:24 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

Time (US & Canada)

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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-10-2021 15:07:24 (UTC-08:00) Pacific 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-10-2021 15:07:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 15:07:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Feb-08-2021 09:37:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-23-2021 10:47:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Transcription Error
Feb-08-2021 09:37:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is NOT willing to retur n for Vaccination 3 OR otherwise not eligible	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-08-2021 08:29:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-23-2021 20:47:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_35
Feb-23-2021 10:47:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Changed data per query
Feb-22-2021 22:14:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Open ed	DM : REVAX CONF CRF is unfrozen. Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the REVAX CONF CRF. Please update or clarify.
Feb-22-2021 14:10:29 (UTC-08:00) Pacific Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Please unlock revax contact form to be updated

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

Canada)				
Feb-22-2021 12:44:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7350350;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Feb-08-2021 08:29:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : ASSE SS EL IGIBI LITY FOR ADDI TION AL V ACCI NATI ON	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1157

Subject No: 11571066

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1157) Paradigm Research

Subject Initials: ---

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-15-2020 12:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-22-2020 10:00:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-22-2020 09:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-15-2020 12:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry
Aug-22-2020 10:00:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/20/2020	Initial Entry
Aug-22-2020 09:57:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/20/2020	Initial Entry

090177e196ae303a\Final\Final On: 01-Apr-2021 04:05 (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: 1157

Site Name: (1157) Paradigm Research

Subject No: 11571066

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 16:01:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jamshid Saleh (b) (4)	Data Entry: Click Here to Enable	Initial Entry