

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/7/2020
----	--------------	---------------------------------------------------------

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10551006]
2.	Birth Date:	(b) (6)/1955
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Aug/7/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/7/2020
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: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Keratoconus, bilateral eyes]
	Start Date:	UNK/UNK/1969
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal allergies]
	Start Date:	UNK/UNK/1958
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Benign Pulmonary Granulomas]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis, bilateral thumbs]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
	Start Date:	Sep/UNK/2018
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Intermittent urinary tract infections]
	Start Date:	UNK/UNK/1973
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Rosacea]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GERD]
	Start Date:	Sep/UNK/1993
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Lactose intolerance]
	Start Date:	UNK/UNK/1993
	Ongoing:	YES

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroid]
	Start Date:	Sep/UNK/1988
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Post-menopausal]
	Start Date:	Dec/UNK/2010
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sulfite allergy]
	Start Date:	UNK/UNK/1999
	Ongoing:	YES

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/7/2020
2.	Weight:	[61.0]
3.	Unit:	kg
4.	Height:	[158.0]
5.	Unit:	cm
6.	Body Mass Index:	[24.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	[]	
5.	Specimen Type:		

Lab Result

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

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition

1.	Randomization Date :	Aug/7/2020
2.	Randomization Number:	[223587]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/7/2020
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	[BP6S51]
5.b	Sample ID	[BP6S52]
5.c	Sample ID	[BP6S53]
5.d	Sample ID	[BPFTRZ]
5.e	Sample ID	[BPFTS0]

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/7/2020
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	[BP6S4Z]
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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/7/2020 10:31
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Aug/26/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[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

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/26/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.2]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Lab Urinalysis

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

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/26/2020
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	[BP6RXN]
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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/26/2020 10:08
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

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Sep/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[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?	YES Ongoing? NO Stop Date: Sep/6/2020
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?	YES Ongoing? NO Stop Date: Sep/6/2020
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
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

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/24/2020
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	[BPV09L]
5.b	Sample ID	[BPV09M]
5.c	Sample ID	[BPFTKC]
5.d	Sample ID	[BPFTKD]

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Sep/24/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Urinary Tract Infection	Sep/1/2020 22:01	NO End Date Time: Sep/6/2020 08:00	Repeating Pages
2.	ADVERSE EVENT	2	Injection site pain	Dec/22/2020 09:02	NO End Date Time: Dec/24/2020 08:00	Repeating Pages
3.	ADVERSE EVENT	3	injection site pain	Jan/11/2021 14:00	NO End Date Time: Jan/12/2021 18:00	Repeating Pages
4.	ADVERSE EVENT	4	chills	Jan/11/2021 19:00	NO End Date Time: Jan/11/2021 20:00	Repeating Pages
5.	ADVERSE EVENT	5	fatigue	Jan/12/2021 12:00	NO End Date Time: Jan/12/2021 15:00	Repeating Pages
6.	ADVERSE EVENT	6	lymph node swelling	Jan/12/2021 12:00	NO End Date Time: Jan/12/2021 15:00	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Urinary Tract Infection]
4.	Start Date Time:	Sep/1/2020 22:01
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/6/2020 08:00
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: [Bacterial Infection]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Dec/22/2020 09:02
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/24/2020 08:00
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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site pain]
4.	Start Date Time:	Jan/11/2021 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/12/2021 18:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[chills]
4.	Start Date Time:	Jan/11/2021 19:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/11/2021 20:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[fatigue]
4.	Start Date Time:	Jan/12/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/12/2021 15:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[lymph node swelling]
4.	Start Date Time:	Jan/12/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/12/2021 15:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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	[]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Medication Error

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

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Influenza Vaccine	Sep/20/2020	Repeating Pages

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza Vaccine]
5.	Date:	Sep/20/2020

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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?	

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	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: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Lab Urinalysis

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

Lab Result

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

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Dec/16/2020
2.	Erroneous Visit	

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

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, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Dec/22/2020
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001**Visit:** V101_VAX3**Form Version:** 10-Dec-2020 02:23**Site No:** 1055**Subject No:** 10551006**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

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

Lab Urinalysis

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

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2PLR]
5.b	Sample ID	[BS3B2Z]
5.c	Sample ID	[BS3B30]

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2PLN]
-----	-----------	----------

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/22/2020 09:02
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/17/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit

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

Header Text: c4591001**Visit:** V102_VAX4**Form Version:** 10-Dec-2020 02:23**Site No:** 1055**Subject No:** 10551006**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44**Form Comments**
eCRF Audit Trail History**Lab Urinalysis**

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

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2PNW]
-----	-----------	----------

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/11/2021 09:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/12/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/12/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551006

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Feb/12/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/24/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-01-2021 16:27:45 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-07-2020 12:25:25 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 30-Jul-2020 21:27
Site No: 1055
Subject No: 10551006
Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1055) Diablo Clinical Research Incorporated
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Aug-07-2020 12:29:37 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe.mpastores)	Not Applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

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Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

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Item	Date	User	Comment
3	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
5	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Dec-22-2020 10:08:53 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

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Form Version: 10-Dec-2020 02:23

Site No: 1055

Subject No: 10551006

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Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

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Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

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Item	Date	User	Comment
3	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

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Site No: 1055

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Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
5	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

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Item	Date	User	Comment
6.a	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

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Item	Date	User	Comment
6.a	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1055

Subject No: 10551006

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Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

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Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

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Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
5	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1055

Subject No: 10551006

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Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

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Item	Date	User	Comment
6.a	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1055

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6.a	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-01-2021 16:27:45 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Megan Pastores	N/A	Mar-01-2021 15:21:53 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-17-2021 07:51:38 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Julie Glazier	N/A	Feb-16-2021 16:44:04 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Helen Stacey	Approved	Feb-12-2021 15:40:02 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Feb-12-2021 10:55:39 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-20-2021 16:25:48 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Dec-18-2020 15:14:48 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Nov-02-2020 13:17:04 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Julie Glazier	N/A	Nov-02-2020 11:49:05 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Oct-12-2020 08:40:16 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Megan Pastores	N/A	Sep-24-2020 10:16:54 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Sep-10-2020 09:53:32 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-07-2020 12:24:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 12:24:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-07-2020 12:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: OBTAINED Date Written Consent Obtained Aug/7/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject ID

Date	Location	User	Value	Reason
Aug-07-2020 12:24:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10551006	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:24:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1955	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-07-2020 12:24:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-07-2020 12:24:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-07-2020 12:24:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: WHITE	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-07-2020 12:25:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/7/2020	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-07-2020 12:25:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-07-2020 12:25:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-07-2020 12:25:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1.a

Date	Location	User	Value	Reason
Aug-07-2020 12:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Keratoconus, bilateral eyes Start Date: UNK/UNK/1969 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 12:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Keratoconus, bilateral eyes	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/1969	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.b

Date	Location	User	Value	Reason
Aug-07-2020 12:45:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History T Seasonal aller erm: gies Start Date: UNK/UNK/1 958 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 12:45:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Seasonal allergies	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/1958	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

I.c

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-07-2020 12:46:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 3 mber: Medical Histo Benign Pulmonary ry Term: Granulomas Start Date: UNK/UNK/2009 Ongoing: YES	Initial Entry

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:02 (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-07-2020 12:46:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Benign Pulmonary Granulomas	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/2009	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-07-2020 12:46:29	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		(autocalc)	Line/MH Number: 4 Medical History Term: Osteoarthritis, bilateral thumbs Start Date: UNK/UNK/2002 Ongoing: YES
----------------------------------------	--	------------	-------------------------------------------------------------------------------------------------------------------------

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 12:46:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> Osteoarthritis, bilateral thumbs	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> UNK/UNK/2002	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-07-2020 12:46:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 5 Medical History Term: Hyperlipidemia	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1055
Subject No: 10551006
Generated By: pfe.levisse
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1055) Diablo Clinical Research Incorporated
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

			Start Date:	Sep/UNK/2018	
			Ongoing:	YES	

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 12:46:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Hyperlipidemia	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/UNK/2018	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-02-2020 11:49:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Line/MH N 6 umber: Medical His Intermittent urinar tory Term: y tract infections Start Date: UNK/UNK/1973 Ongoing: YES	Changed Information (DELETED)

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Aug-07-2020 12:47:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Line/MH N umber: 6 Medical History Term: Intermittent urinary tract infections Start Date: UNK/UNK/1973 Ongoing: YES	Changed Information
Aug-07-2020 12:47:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 6 Medical History Term: Occasional urinary tract infections Start Date: UNK/UNK/1973 Ongoing: YES	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.f Line/MH Number:

Date	Location	User	Value	Reason
Nov-02-2020 11:49:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 6	Changed Information (DELETED)
Aug-07-2020 12:47:20 (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
Nov-02-2020 11:49:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Intermittent urinary tract infections	Changed Information (DELETED)
Aug-13-2020 22:37:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (pfe.liaukf)	Query 1: Closed	Response satisfies query
Aug-13-2020 11:50:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	Original value is correct
Aug-12-2020 06:56:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Per IC3 and Criteria for Temporary Delay of Enrolment (Protocol 5.5), please confirm stability of symptoms within 6 weeks of enrolment and no acute event within 48h before study intervention administration
Aug-07-2020 12:47:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Intermittent urinary tract infections	Changed Information
Aug-07-2020 12:47:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Occasional urinary tract infections	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.f Start Date:

Date	Location	User	Value	Reason
Nov-02-2020 11:49:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> UNK/UNK/1973	Changed Information (DELETED)
Aug-07-2020 12:47:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> UNK/UNK/1973	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Nov-02-2020 11:49:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> YES	Changed Information (DELETED)
Aug-07-2020 12:47:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-07-2020 12:47:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number 7 : Medical History T Rosacea erm: Start Date: UNK/UNK/2 010 Ongoing: YES	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1055
Subject No: 10551006
Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1055) Diablo Clinical Research Incorporated
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:47:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 12:47:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Rosacea	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:47:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/2010	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:47:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-07-2020 12:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Te GERD rm: Start Date: Sep/UNK/19 93 Ongoing: YES	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 12:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: GERD	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/UNK/1993	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

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<i>I.i</i>				
Date	Location	User	Value	Reason
Aug-07-2020 12:48:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: r: Medical History Term: Start Date: Ongoing:	Initial Entry Lactose intolerance UNK/UNK/1993 YES

<i>I.i Line/MH Number:</i>				
Date	Location	User	Value	Reason
Aug-07-2020 12:48:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

<i>I.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Aug-07-2020 12:48:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Lactose intolerance	Initial Entry

<i>I.i Start Date:</i>				
Date	Location	User	Value	Reason
Aug-07-2020 12:48:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/1993	Initial Entry

<i>I.i Ongoing:</i>				
Date	Location	User	Value	Reason
Aug-07-2020 12:48:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.j

Date	Location	User	Value	Reason
Aug-07-2020 12:49:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Te Hypothyroid rm: Start Date: Sep/UNK/19 88 Ongoing: YES	Initial Entry

I.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 12:49:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Hypothyroid	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/UNK/1988	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

I.k

Date	Location	User	Value	Reason
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Aug-07-2020 12:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 11 : Medical History Term: Post-menopausal Start Date: Dec/UNK/2010 Ongoing: YES	Initial Entry
-------------------------------------------------------------------	-----------------	-------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 12:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Post-menopausal	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Dec/UNK/2010	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Aug-07-2020 12:49:51 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)			Line/MH Number 12 : Medical History T Sulfite allerg erm: y Start Date: UNK/UNK/1 999 Ongoing: YES	
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1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sulfite allergy	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/1999	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/7/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 61.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 158.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24.4	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier:: 1 Temperature: 36.7 Temperature Unit: C Temperature Location:: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 36.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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3. Collection Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:29:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-07-2020 12:28:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-07-2020 12:28:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-07-2020 12:28:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-07-2020 12:28:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT DONE	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-07-2020 12:30:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/7/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:30:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 223587	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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-07-2020 12:36:28 (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-07-2020 12:36:28 (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-07-2020 12:36:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-07-2020 12:36:28 (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-07-2020 12:36:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Aug/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-07-2020 12:36:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP6S51	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 12:36:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6S51	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-07-2020 12:36:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP6S52	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 12:36:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6S52	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-07-2020 12:37:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP6S53	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 12:37:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6S53	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-07-2020 12:37:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPFTRZ	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 12:37:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPFTRZ	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-07-2020 12:37:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPFTS0	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 12:37:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPFTS0	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-07-2020 12:38:00 (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-07-2020 12:38:00 (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-07-2020 12:38:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-07-2020 12:38:00 (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-07-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Aug/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-07-2020 12:38:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP6S4Z	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 12:38:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6S4Z	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (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-07-2020 12:32:45 (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-07-2020 12:32:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/7/2020 10:31	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (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-07-2020 12:32:45 (UTC-08:00) Pacific	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:04
Site No: 1055
Subject No: 10551006
Generated By: pfe.levissc
Form: VACCINATION - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1055) Diablo Clinical Research Incorporated
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (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-07-2020 12:32:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-07-2020 12:33:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES - REACTOGENICITY E-D IARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-26-2020 11:11:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/26/2020	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:30**Site No:** 1055**Subject No:** 10551006**Generated By:** pfe.levissc**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[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
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the la O st day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-27-2020 09:24:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Symptom:: FA TI	Transcription Error

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

			<p style="text-align: right;">G U E</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO</p>	
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	<p><u>Data Entry:</u></p> <p>Symptom:: F A T I G U E</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES</p> <p>Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>Au g/1 1/2 020</p>	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.b Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 14:07:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Aug-27-2020 09:24:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-27-2020 09:24:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Transcription Error
Aug-27-2020 08:04:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Isaac Arasavalli (pfe.arasai)	Query 1: Opened	eDiary: Per eDiary records, FATIGUE is not reported on Last day (Day 7) however the last day in inform is entered as 'Yes' for the same. Please verify and update. Else, clarify. Thanks.
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: YES Ongoing? NO Stop Date: Aug/11/2020	Initial Entry

2.c

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-27-2020 09:24:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Transcription Error
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Symptom:: HEADACHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: Aug/1 2/2 020	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.c Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Aug-27-2020 14:07:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Aug-27-2020 09:24:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-27-2020 09:24:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Transcription Error
Aug-27-2020 08:05:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Isaac Arasavalli (pfe.arasai)	Query 1: Opened	eDiary: Per eDiary records, HEADACHE is not reported on Last day (Day 7) however the last day in inform is entered as 'Yes' for the same. Please verify and update. Else, clarify. Thanks.
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Ongoing? NO Stop Date: Aug/12/2020	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.d

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.e Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic s NO ymptoms present on the last day the Subject Diar y was completed?:	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

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2.g

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste mic symptoms pres ent on the last day t he Subject Diary w as completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NEW OR WORSE NED MUSC LE 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
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Symptom:: NEW O R WORS ENED J OINT P AIN	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (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
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Injection Site Reaction:: RE DN ESS	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Aug-26-2020 11:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/26/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-26-2020 11:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Record Identifier:: 1 Temperature: 36.2 Temperature Unit: C Temperature Location:: FOREHE AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-26-2020 11:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Aug-26-2020 11:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 36.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-26-2020 11:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: C	Initial Entry

2.a Temperature Location:

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-26-2020 11:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sponsor-Defined I Not Appli dentifier: cable Test:: Not Appli cable Result:: Not Appli cable Not Done:: Not Appli cable	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Not Applicable	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-27-2020 09:00:20 (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-27-2020 09:00:20 (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-27-2020 09:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 09:00:20 (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-27-2020 09:00:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Aug/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 09:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample ID: BP6RXN	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 09:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RXN	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (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-26-2020 11:42:18 (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-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/26/2020 10:08	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (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-26-2020 11:42:18 (UTC-08:00) Pacific	ACV0PFEINFP6000	Megan Pastores	Data Entry: LEFT	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)

(pfe.mpastores)

7. Route:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-24-2020 10:16:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Sep/24/2020	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551006**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:44[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-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the la O st day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	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-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Symptom:: FATIGU E	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</p> <p>YES Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>Sep/6/2020</p>	
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2.b Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	<p>Data Entry: YES Ongoing?</p> <p>NO</p> <p>Stop Date: Sep/6/2020</p>	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	<p>Data Entry: Symptom:: HE AD AC HE</p>	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	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-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Symptom: CHILLS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Stop Date: : Sep/6/2020	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.d Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	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-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: YES Ongoing? NO Stop Date: Sep/6/2020	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Symptom:: VO MIT ING Were fever or systemic s NO ymptoms present on the last day the Subject Dia ry was completed?:	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.e Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	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-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic s NO ymptoms present on the last day the Subject Diar y was completed?:	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	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-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

2.g

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	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-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (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-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Injection Site Reaction:: RE DN ESS	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	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-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	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-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	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-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	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-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-24-2020 15:27:49 (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-24-2020 15:27:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-24-2020 15:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 15:27:49 (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-24-2020 15:27:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Sep/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-24-2020 15:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPV09L	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPV09L	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-24-2020 15:28:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPV09M	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:28:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPV09M	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-24-2020 15:28:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPFTKC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:28:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPFTKC	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-24-2020 15:28:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPFTKD	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:28:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPFTKD	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-24-2020 10:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Sep/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-24-2020 10:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-24-2020 10:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: COMPLETED	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (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
Sep-24-2020 13:16:17 (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
Nov-03-2020 04:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	MH deleted
Nov-02-2020 11:49:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	AE of UTI is new occurrence and not part of baseline medical history
Nov-01-2020 21:23:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 1: Opened	The AE Urinary Tract Infection was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term.
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Urinary Tract Infection	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Sep/1/2020 22:01	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO End Date Time: Sep/6/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	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
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	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
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Bacterial Infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (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
Jan-11-2021 10:04:02 (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
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Dec/22/2020 09:02	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO End Date Time: Dec/24/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	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
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	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
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (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
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/11/2021 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-16-2021 16:44:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date Time: Jan/12/2021 18:00	Transcription Error
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO End Date Time:	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Jan/12/2021 08:00

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> chills	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> Jan/11/2021 19:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> NO End Date Time: Jan/11/2021 20:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> fatigue	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> Jan/12/2021 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> NO End Date Time: Jan/12/2021 15:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry
-------------------------------------------------------------------	-----------------	--------------------------------	--------------------------	---------------

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (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
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: lymph node swelling	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/12/2021 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO End Date Time: Jan/12/2021 15:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Sep-24-2020 15:50:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Sep-24-2020 15:50:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Sep-24-2020 15:50:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Sep-24-2020 15:50:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Sep-24-2020 15:50:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Influenza Vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:50:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Sep/20/2020	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-18-2020 15:14:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Dec/16/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Dec-18-2020 15:15:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 15:15:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-18-2020 15:15:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-22-2020 10:08:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Dec/22/2020	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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I. Consent Was:

Date	Location	User	Value	Reason
Dec-22-2020 10:08:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: OBTAINED Date Written Consent Obtained Dec/22/2020	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-22-2020 10:09:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Dec/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-22-2020 10:09:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-22-2020 10:09:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: COMPLETED	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sponsor-Defined I dentifier: Test:: Result:: Not Done::	Not Appli cable Not Appli cable Not Appli cable Not Appli cable	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Dec-22-2020 15:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 15:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-22-2020 15:50:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 15:50:31 (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.
Dec-22-2020 15:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection: Dec/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 15:50:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID: BR2PLR	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 15:50:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> BR2PLR	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-22-2020 15:50:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> Sample ID: BS3B2Z	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 15:50:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> BS3B2Z	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-22-2020 15:51:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> Sample ID: BS3B30	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 15:51:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> BS3B30	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551006**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 16:08:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 16:08:54 (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
Dec-22-2020 16:09:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 16:08:54 (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.
Dec-22-2020 16:08:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection: Dec/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 16:09:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID: BR2PLN	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 16:09:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2PLN	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (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
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Dec/22/2020 09:02	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (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
Dec-22-2020 10:11:26 (UTC-08:00) Pacific	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: LEFT	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-01-2021 15:21:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Dec/17/2020	Transcription Error
Dec-18-2020 15:15:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Dec/16/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-18-2020 15:15:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-11-2021 09:57:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/11/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sponsor-Defined I dentifier: Test:: Result:: Not Done::	Not Appli cable Not Appli cable Not Appli cable Not Appli cable	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Jan-11-2021 15:09:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-11-2021 15:09:51 (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
Jan-11-2021 15:10:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 15:09:51 (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.
Jan-11-2021 15:09:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection: Jan/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-11-2021 15:10:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID: BR2PNW	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 15:10:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2PNW	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551006

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (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
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/11/2021 09:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (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
Jan-11-2021 10:00:48 (UTC-08:00) Pacific	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: LEFT	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-12-2021 10:55:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/12/2021	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Contact Type:

Date	Location	User	Value	Reason
Feb-12-2021 10:56:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-12-2021 10:56:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Contact: Feb/12/2021	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** FURTHER_VACCINATION_EOT -
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551006**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-16-2021 03:44:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ashwini Devi Subhash (pfe.subhaa)	Query 1: Clo sed	incorrect
Feb-12-2021 19:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7250357;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Feb-12-2021 10:56:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry : Feb/1 2/202 1	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-12-2021 10:56:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-12-2021 10:56:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551006

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject Status

Date	Location	User	Value	Reason
Sep-24-2020 10:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-07-2020 12:30:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-07-2020 12:25:53 (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
Sep-24-2020 10:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/24/2020	Initial Entry
Aug-07-2020 12:30:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/7/2020	Initial Entry
Aug-07-2020 12:25:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/7/2020	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Sep-10-2020 08:38:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae4079\Final\Final On: 01-Apr-2021 05:41 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/10/2020
----	--------------	----------------------------------------------------------

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10551012]
2.	Birth Date:	(b) (6)/1988
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 _____
----	----------------------------------------	-------------------------

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/10/2020
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: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	Jan/1/1996
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Seasonal allergies]
	Start Date:	Jan/1/1993
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypothyroid]
	Start Date:	Mar/6/2000
	Ongoing:	YES

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Zithromax allergy]
	Start Date:	Dec/UNK/1998
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/10/2020
2.	Weight:	[59.6]
3.	Unit:	kg
4.	Height:	[156.0]
5.	Unit:	cm
6.	Body Mass Index:	[24.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/10/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/10/2020
2.	Randomization Number:	[43756]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/10/2020
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	[BP6S5W]
5.b	Sample ID	[BP6S5X]
5.c	Sample ID	[BP6S5Y]
5.d	Sample ID	[BPFTSC]
5.e	Sample ID	[BPFTSD]

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/10/2020
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	[BP6S5S]
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/10/2020 12:10
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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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
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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

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

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[34.6]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
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	[BP91S9]
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/1/2020 14:31
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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
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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/29/2020
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	[BPV0CJ]
5.b	Sample ID	[BPV0CK]
5.c	Sample ID	[BPFTLC]
5.d	Sample ID	[BPFTLD]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P7G]
5.b	Sample ID	[BS3BBR]
5.c	Sample ID	[BS3BBP]

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V6_MONTH24_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	
----	----------------------------------------------------------------------	--

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

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

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

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Sep/29/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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 **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Left supraclavicular adenopathy	Sep/2/2020 07:00	NO End Date Time: Sep/3/2020 07:00	Repeating Pages
2.	ADVERSE EVENT	2	Shingles	Feb/8/2021 19:00	YES	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left supraclavicular adenopathy]
4.	Start Date Time:	Sep/2/2020 07:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/3/2020 07:00
6.	Toxicity Grade:	1

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

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Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[2]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Shingles]	Comments
4.	Start Date Time:	Feb/8/2021 19:00	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	2	

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	NO
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p>If Other, specify: [viral infection]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[]

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Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	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: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Medication Error

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	influenza vaccine	Sep/30/2020	Repeating Pages

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[influenza vaccine]
5.	Date:	Sep/30/2020

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

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Concomitant Medications

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Radiation Treatment

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

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

Vital Signs Details

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

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

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/29/2020

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-25-2021 16:22:18 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-10-2020 13:16:12 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
3	Feb-25-2021 10:29:31 (UTC-08:00) Pacific Time (US & Canada)	Lana Norman (pfe.lnorman)	one dermatome and no prior history of shingles

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-25-2021 16:22:18 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Lana Norman	N/A	Feb-25-2021 10:29:31 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-24-2021 08:03:52 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Feb-23-2021 15:53:47 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-23-2021 15:02:24 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Elle Billman	N/A	Feb-23-2021 10:58:29 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-27-2021 17:04:55 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Julie Glazier	N/A	Jan-27-2021 13:04:05 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Oct-12-2020 08:49:52 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** Investigator Signature -
Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature
History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:44**Affidavit:**

By my dated signature below, I, HelenStacey, 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.

Julie Glazier	N/A	Sep-29-2020 13:12:29 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Sep-10-2020 09:56:14 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-10-2020 13:15:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-10-2020 13:15:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-10-2020 13:15:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: OBTAINED Date Written Consent Obtained Aug/10/2020	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-10-2020 13:15:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10551012	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-10-2020 13:15:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1988	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-10-2020 13:15:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-10-2020 13:15:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-10-2020 13:15:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: WHITE	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-10-2020 13:16:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/10/2020	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-10-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/10/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-10-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-10-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)***1.a***

Date	Location	User	Value	Reason
Aug-10-2020 13:20:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 1 mber: Medical Histo Asthm ry Term: a Start Date: Jan/1/ 1996 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 13:20:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 22:38:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (pfe.liaukf)	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-13-2020 11:50:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	Original value is correct
Aug-12-2020 04:58:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Per IC3, please confirm stability of symptoms prior to study enrolment; that no significant change in therapy or hospitalization for worsening of disease within 6 weeks of enrolment. Also, confirm EC13 reviewed (systemic corticosteroid use)
Aug-10-2020 13:20:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Asthma	Initial Entry

1.a Start Date:

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-10-2020 13:20:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Jan/1/1996	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 13:20:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-10-2020 13:21:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 2 umber: Medical Hi Seasonal story Term: allergies Start Date: Jan/1/19 93 Ongoing: YES	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:06 (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-10-2020 13:21:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Seasonal allergies	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Jan/1/1993	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:06	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00)
Pacific Time (US
& Canada)

I.c

Date	Location	User	Value	Reason
Aug-10-2020 13:21:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 3 mber: Medical Hist Hypoth ory Term: yroid Start Date: Mar/6/ 2000 Ongoing: YES	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-10-2020 13:21:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Hypothyroid	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Mar/6/2000	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:32	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00)
Pacific Time (US
& Canada)

1.d

Date	Location	User	Value	Reason
Aug-10-2020 13:21:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 4 Medical Hi story Term: x allergy Start Date: Dec/UN K/1998 Ongoing: YES	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-10-2020 13:21:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Zithromax allergy	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Dec/UNK/1998	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:59	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/10/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 59.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 156.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier: 1 Temperature: 36.8	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

			Temperatur C e Unit: Temperatur FORE e Location:: HEAD	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 36.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

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7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/10/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
-------------------------------------------------------------------------	-----------------	-------------------------	----------------------------------	---------------

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NEGATIVE	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-10-2020 13:17:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/10/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 43756	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-10-2020 15:09:43 (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-10-2020 15:09:43 (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-10-2020 15:09:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-10-2020 15:09:43 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-10-2020 15:09:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Aug/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-10-2020 15:09:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID BP6S5 : W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:09:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6S5W	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-10-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID BP6S5 : X	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6S5X	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-10-2020 15:10:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID BP6S5 : Y	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:10:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6S5Y	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.d

Date	Location	User	Value	Reason
Aug-10-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID BPFTS : C	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPFTSC	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-10-2020 15:10:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID BPFTS : D	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

5.e Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:10:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPFTSD	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-10-2020 15:11:02 (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-10-2020 15:11:02 (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-10-2020 15:11:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-10-2020 15:11:02 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-10-2020 15:11:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Aug/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-10-2020 15:11:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID BP6S5S :	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:11:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6S5S	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (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-10-2020 13:18:03 (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
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/10/2020 12:10	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (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-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-10-2020 13:18:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES - REACTOGEN ICITY E-DIARY CO LLECTED FOR THI S SUBJECT	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 15:31:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/1/2020	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: F E V E R Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: FA TI G U E Were fever or s N ystemic sympto O ms present on t he last day the S ubject Diary wa s completed?:	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.b Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: C	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)			HI L L S N O	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.d Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: VO MI TI NG Were fever or s NO ystemic sympto ms present on t he last day the Subject Diary was completed ?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.f

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: DI AR RH EA Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed? :	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.f Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: NEW OR W ORSE NED MUS CLE P AIN	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

			Were fever or NO r systemic sy mptoms pre sent on the l ast day the S ubject Diary was complet ed?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NEW OR WORSEN ED 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-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-01-2020	ACV0PFEINFP6000	Julie Glazier	Data Entry:	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

15:31:58
(UTC-08:00)
Pacific Time (US
& Canada)

(pfe.jglazier)

Symptom:: NEW
OR W
ORSE
NED
JOIN
T PAI
N

Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.h Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NEW OR WORSEN ED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (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
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry
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5.a

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Injection Site Reaction:: RE D NE SS Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: REDNESS	Initial Entry

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Injection Site SW Reaction:: EL LI NG Were injection NO site reactions p resent on the la st day the Subj ect Diary was c ompleted?:	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Injection Site Reaction:: PAI N AT INJE CTI ON SITE	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

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Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

			Were injections present on the last day the Subject Diary was completed?:	NO
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/1/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier:: Temperature: 34.6 Temperature Unit: Temperature Location:: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.a Temperature:

Date	Location	User	Value	Reason
Sep-02-2020 01:49:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Closed	As per site confirmation
Sep-01-2020 15:32:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	correct as entered, not clinically significant
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 34.6 C is outside of Normal Range 36.1 - 37.5 C.
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 34.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/1/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NEGATIVE	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 15:57:26 (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-01-2020 15:57:26 (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-01-2020 15:57:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 15:57:26 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 15:57:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 15:57:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP91S9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 15:57:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP91S9	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (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-01-2020 15:34:02 (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
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/1/2020 14:31	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (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-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-29-2020 13:12:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/29/2020	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:44[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-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: F E V E R Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: FA TI G U E Were fever or s N ystemic sympto O ms present on t he last day the S ubject Diary wa s completed?:	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Site No: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

2.b Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: C	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)			HI L L S N O	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.d Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: VO MI TI NG Were fever or s NO ystemic sympto ms present on t he last day the Subject Diary was completed ?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

2.f

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: DI AR RH EA Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed? :	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

2.f Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Symptom:: NEW OR W ORSE NED MUS CLE P AIN	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

			Were fever or NO r systemic sy mptoms pre sent on the l ast day the S ubject Diary was complet ed?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NEW OR WORSEN ED 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-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-29-2020	ACV0PFEINFP6000	Julie Glazier	Data Entry:	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

13:14:12
(UTC-08:00)
Pacific Time (US
& Canada)

(pfe.jglazier)

Symptom:: NEW
OR W
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**Were fever o NO
r systemic sy
mptoms pres
ent on the la
st day the Su
bject Diary
was complet
ed?:**

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

2.h Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NEW OR WORSEN ED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (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
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry
-------------------------------------------------------------------------	-----------------	---------------------------------	----------------------------	---------------

5.a

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Injection Site Reaction:: RE D NE SS Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: REDNESS	Initial Entry

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

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Injection Site SW Reaction:: EL LI NG Were injection NO site reactions p resent on the la st day the Subj ect Diary was c ompleted?:	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Injection Site PAI Reaction:: N AT INJE CTI ON SITE	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

			Were injections present on the last day the Subject Diary was completed?:	NO
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-29-2020 15:19:45 (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-29-2020 15:19:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-29-2020 15:19:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 15:19:45 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-29-2020 15:19:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Sep/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 15:19:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPV0C D: J	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 15:19:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPV0CJ	Initial Entry

5.b

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-29-2020 15:20:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPV0C D: K	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 15:20:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPV0CK	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 15:20:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPFTL D: C	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 15:20:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFTLC	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-29-2020 15:20:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPFTL D: D	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 15:20:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFTLD	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 10:58:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/23/2021	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Feb-23-2021 15:53:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 15:53:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-23-2021 15:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 15:53:47 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-23-2021 15:53:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection : Feb/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-23-2021 15:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BR2P7 : G	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2P7G	Initial Entry

5.b

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-23-2021 15:54:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample I BS3BB D: R	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:54:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BS3BBR	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-23-2021 15:54:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BS3BB : P	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551012

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:54:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BS3BBP	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-29-2020 13:19:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-29-2020 13:19:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-29-2020 13:19:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (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
Sep-29-2020 13:18:39 (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
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Left supraclavicular a denopathy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/2/2020 07:00	Initial Entry
-------------------------------------------------------------------------	-----------------	---------------------------------	----------------------------------------	---------------

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date Time: Sep/3/2020 07:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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).

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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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

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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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (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
Feb-23-2021 11:04:15 (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
Feb-25-2021 12:15:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	Response satisfies query
Feb-25-2021 10:29:08	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 1: Answered	one dermatome

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				and no prior history of shingles
Feb-25-2021 06:34:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	clinical: pls advise if one or more than one dermatome involved, and if subject has prior history of shingles.
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Shingles	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/8/2021 19:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551012**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44(UTC-08:00)
Pacific Time (US
& Canada)**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	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
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	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
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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

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Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-23-2021 13:33:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT RELATED If Not Related to s tudy treatment(s), this event is due to : OTHER <i>If Other, specif y:</i> viral infection	New Information
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT RELATED If Not Related to s tudy treatment(s), this event is due to : OTHER	Initial Entry

10. Latest Action Taken with Study Treatment:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT APPLICABLE	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-25-2021 12:14:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	Response satisfies query
Feb-25-2021 10:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 1: Answered	none of the meds taken for this event were steroids
Feb-25-2021 06:36:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	clinical: did subject receive steroids? if so please advise of dose and duration.Thanks
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

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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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT RECOVERED /NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-23-2021 11:02:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-23-2021 11:02:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-23-2021 11:02:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-23-2021 11:02:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-23-2021 11:02:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Feb-23-2021 11:02:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sep/30/2020	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-27-2021 13:04:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Jan/25/2021	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Jan-27-2021 13:04:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-27-2021 13:04:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-27-2021 13:04:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Participant is willin g to return for Vacc ination 3 Participant is: eligible and NO T confirmed to h ave received onl y placebo at Vac	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

			ination 1/2	
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090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-27-2021 13:04:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Jan/25/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-27-2021 13:04:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject Status

Date	Location	User	Value	Reason
Sep-29-2020 13:19:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-10-2020 13:17:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-10-2020 13:16:24 (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
Sep-29-2020 13:19:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/29/2020	Initial Entry
Aug-10-2020 13:17:44	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/10/2020	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
Aug-10-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/10/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551012

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Casebook Signature

Date	Location	User	Value	Reason
Sep-10-2020 08:39:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae407b\Final\Final On: 01-Apr-2021 05:41 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/20/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10551084]
2.	Birth Date:	(b) (6) 1989
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 _____
----	----------------------------------------	-------------------------

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1055

Subject No: 10551084

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Form Comments

Medical History Details

1.	Line/MH Number:	Not Applicable _____ []
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	Not Applicable _____ []
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/20/2020
2.	Weight:	[80.4]
3.	Unit:	kg
4.	Height:	[171.2]
5.	Unit:	cm
6.	Body Mass Index:	[27.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/20/2020
2.	Randomization Number:	[59409]
3.	Randomization Group:	[]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551084**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[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	[BP6RSR]
5.b	Sample ID	[BP6RSS]
5.c	Sample ID	[BP6RST]
5.d	Sample ID	[BPFTY5]
5.e	Sample ID	[BPFTY6]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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	[BP6RSH]
-----	-----------	----------

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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 13:33
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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/8/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551084**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9233]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/8/2020 12:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551084**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPV0JM]
5.b	Sample ID	[BPV0JN]
5.c	Sample ID	[BPFTR9]
5.d	Sample ID	[BPFTRB]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/2/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P8C]
5.b	Sample ID	[BSG7K5]
5.c	Sample ID	[BSG7K6]

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551084**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551084**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**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: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	
----	----------------------------------------------------------------------	--

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Illness Details

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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

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

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

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Unplanned Assessments

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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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 **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Warm feeling of neck and head	Aug/20/2020 14:05	NO End Date Time: Aug/21/2020 09:00	Repeating Pages
2.	ADVERSE EVENT	2	Fatigue	Aug/20/2020 15:30	NO End Date Time: Aug/21/2020 08:00	Repeating Pages
3.	ADVERSE EVENT	3	Low grade fever	Sep/8/2020 14:00	NO End Date Time: Sep/9/2020 07:00	Repeating Pages
4.	ADVERSE EVENT	4	Fatigue	Sep/8/2020 14:00	NO End Date Time: Sep/9/2020 07:00	Repeating Pages
5.	ADVERSE EVENT	5	Exposure during pregnancy	Feb/4/2021 UNK:UNK	YES	Repeating Pages

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Warm feeling of neck and head]
4.	Start Date Time:	Aug/20/2020 14:05
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/21/2020 09:00
6.	Toxicity Grade:	1

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Aug/20/2020 15:30
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/21/2020 08:00
6.	Toxicity Grade:	1

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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
12.	Was a Non-Drug Treatment given?	NO

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Low grade fever]
4.	Start Date Time:	Sep/8/2020 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/9/2020 07:00
6.	Toxicity Grade:	1

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Sep/8/2020 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/9/2020 07:00
6.	Toxicity Grade:	1

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

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Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[5]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure during pregnancy]	
4.	Start Date Time:	Feb/4/2021 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551084**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

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: [sexual intercourse]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	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: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Medication Error

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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flu Vaccine	Oct/9/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flu Vaccine]
5.	Date:	Oct/9/2020

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Radiation Treatment

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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

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

Vital Signs Details

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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

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

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551084**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551084**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**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 - **Form:** DATE OF VISIT

Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/17/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/8/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-12-2021 09:53:05 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-20-2020 15:38:21 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe.mpastores)	Not Applicable <hr/> Not Applicable

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-20-2020 15:41:23 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe.mpastores)	Not Applicable <hr/> Not Applicable

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
6	Mar-10-2021 11:46:42 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable <hr/> Not Applicable

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-12-2021 09:53:05 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Julie Glazier	N/A	Mar-11-2021 13:29:58 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Mar-10-2021 18:48:00 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Julie Glazier	N/A	Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Mar-02-2021 19:21:41 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Megan Pastores	N/A	Mar-02-2021 10:00:24 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-20-2021 16:59:46 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Dec-17-2020 13:35:41 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Oct-21-2020 16:44:39 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-20-2020 15:34:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 15:34:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-20-2020 15:34:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: OBTAINED Date Written Cons ent Obtained Aug/20/2020	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-20-2020 15:33:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10551084	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-20-2020 15:33:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1989	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-20-2020 15:36:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-20-2020 15:36:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT HISPANIC O R LATINO(A) OR OF SPANISH ORI GIN	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------------------	---------------------------------------------------------------------------------	---------------

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

Date	Location	User	Value	Reason
Aug-20-2020 15:36:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: ASIAN	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-20-2020 15:38:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/20/2020	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-20-2020 15:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-20-2020 15:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-20-2020 15:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: COMPLETED	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/20/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 80.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 171.2	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27.4	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Record Identifier: Temperature: 36.9	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

			Temperatu C re Unit: Temperatu FORE re Locatio HEA n:: D	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 36.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: C	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: FOREHEAD	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-20-2020 15:43:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/20/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-20-2020 15:43:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 59409	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-21-2020 09:08:42 (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-21-2020 09:08:42 (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-21-2020 09:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 09:08:42 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-21-2020 09:08:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-21-2020 09:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RS D: R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RSR	Initial Entry

5.b

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-21-2020 09:09:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RS D: S	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:09:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RSS	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-21-2020 09:09:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RS D: T	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:09:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RST	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-21-2020 09:09:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPFTY D: 5	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:09:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFTY5	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-21-2020 09:10:16	ACV0PFEINFP6000	Megan Pastores	Data Entry: Sample I BPFTY	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		(pfe.mpastores)	D: 6	
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:10:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFTY6	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-21-2020 08:51:34 (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-21-2020 08:51:34 (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-21-2020 08:51:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 08:51:34 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-21-2020 08:51:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-21-2020 08:51:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RS D: H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 08:51:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RSH	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (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-20-2020 15:44:10 (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
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090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551084

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/20/2020 13:33	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (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-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-20-2020 15:44:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO - REACTOGE NICITY E-DIARY NOT COLLECTED FOR THIS SUBJE CT	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-08-2020 13:12:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/8/2020	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-08-2020 13:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location:: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-08-2020 13:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

2.a Temperature:

Date	Location	User	Value	Reason
Sep-08-2020 13:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 36.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-08-2020 13:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-08-2020 13:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-08-2020 16:47:27 (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-08-2020 16:47:27 (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-08-2020 16:47:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-08-2020 16:47:27 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-08-2020 16:47:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Sep/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-08-2020 16:47:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP9233	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 16:47:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP9233	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (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-08-2020 13:13:06 (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
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090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/8/2020 12:00	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (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-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 12:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Oct/8/2020	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-08-2020 15:39:10 (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-08-2020 15:39:10 (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-08-2020 15:39:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 15:39:10 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 15:39:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-08-2020 15:39:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPV0J D: M	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 15:39:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPV0JM	Initial Entry

5.b

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-08-2020 15:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPV0J D: N	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 15:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPV0JN	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-08-2020 15:39:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPFTR D: 9	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 15:39:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFTR9	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-08-2020 15:39:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPFTR D: B	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 15:39:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFTRB	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 10:00:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Mar/2/2021	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Mar-02-2021 15:49:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-02-2021 15:49:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-02-2021 15:49:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 15:49:31 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Mar-02-2021 15:49:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Mar/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-02-2021 15:49:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BR2P8 D: C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 15:49:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BR2P8C	Initial Entry

5.b

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Header Text: c4591001

Visit: V4_MONTH6_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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-02-2021 15:49:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BSG7K D: 5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 15:49:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BSG7K5	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-02-2021 15:50:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BSG7K D: 6	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551084

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 15:50:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BSG7K6	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-08-2020 12:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Oct/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-08-2020 12:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-08-2020 12:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

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Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

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Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

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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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (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
Sep-08-2020 13:15:50 (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
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Warm feeling of neck and head	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/20/2020 14:05	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date Time: Aug/21/2020 09:0 0	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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).

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT APPLICABLE	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-08-2020 13:17:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Transcription Error
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)

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

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (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
Sep-08-2020 13:16:47 (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
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Fatigue	Initial Entry

4. Start Date Time:

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Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/20/2020 15:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date Time: Aug/21/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.lewissc

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medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

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Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (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
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Low grade fever	Initial Entry

4. Start Date Time:

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/8/2020 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO End Date Time: Sep/9/2020 07:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT APPLICABL E	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RECOVERED/RES OLVED	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Oct-08-2020 12:28:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 12:28:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Transcription Error
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candida te	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	<u>Data Entry:</u> YES	Initial Entry
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090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (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
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Fatigue	Initial Entry

4. Start Date Time:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/8/2020 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO End Date Time: Sep/9/2020 07:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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

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Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

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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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (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 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Exposure during pregnancy	Initial Entry

4. Start Date Time:

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-11-2021 13:29:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Feb/4/2021 UNK:U NK	Changed Information
Mar-10-2021 14:25:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Jan/28/2021 UNK:U NK	New Information
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Jan/21/2021 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-10-2021 11:46:42	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00)
Pacific Time (US
& Canada)

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 12:25:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

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Mar-10-2021 12:25:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify</i> : sexual intercourse	New Information
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-10-2021	ACV0PFEINFP6000	Julie Glazier	Data Entry:	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

11:46:17 (UTC-08:00) Pacific Time (US & Canada)		(pfe.jglazier)	NO	
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 01:14:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rose Madelein (pfe.rose19)	Query 1: Closed	Response satisfies query
Mar-10-2021 12:26:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	correct as entered per guidance given regarding this situation
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Exposure during pregnancy:

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

& Canada)				Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNKNOWN	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Mar-02-2021 10:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Mar-02-2021 10:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Mar-02-2021 10:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Mar-02-2021 10:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Mar-02-2021 10:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Flu Vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Mar-02-2021 10:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Oct/9/2020	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-17-2020 13:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Dec/17/2020	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-08-2021 09:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	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
Dec-17-2020 13:37:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-17-2020 13:37:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Dec/17/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITIO NAL VACCINATIO N	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-08-2020 12:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-20-2020 15:43:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-20-2020 15:39:29 (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-08-2020 12:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/8/2020	Initial Entry
Aug-20-2020 15:43:17	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/20/2020	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
Aug-20-2020 15:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/20/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551084

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 15:16:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae408d\Final\Final On: 01-Apr-2021 05:42 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/24/2020
----	--------------	----------------------------------------------------------

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10551092]
2.	Birth Date:	(b) (6)/1972
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:	

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 _____
----	----------------------------------------	-------------------------

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/24/2020
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: 1055

Subject No: 10551092

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Form Comments](#)

Medical History Details

1.	Line/MH Number:	Not Applicable _____ []
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	Not Applicable _____ []
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/24/2020
2.	Weight:	[70.0]
3.	Unit:	kg
4.	Height:	[174.5]
5.	Unit:	cm
6.	Body Mass Index:	[23.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/24/2020
2.	Randomization Number:	[61282]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
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	[BP6RTV]
5.b	Sample ID	[BP6RTW]
5.c	Sample ID	[BP6RTX]
5.d	Sample ID	[BPFTYP]
5.e	Sample ID	[BPFTYR]

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
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	[BP6RTN]
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/24/2020 11:38
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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/15/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/15/2020
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	[BP922D]
-----	-----------	----------

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/15/2020 14:13
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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551092**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/13/2020
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	[BR2PBP]
5.b	Sample ID	[BR2PBR]
5.c	Sample ID	[BS89X1]
5.d	Sample ID	[BS89X2]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P9D]
5.b	Sample ID	[BSG7LS]
5.c	Sample ID	[BSG7LT]

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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 Version: 20-Feb-2021 02:17

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	
----	----------------------------------------------------------------------	--

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

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

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

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Unplanned Assessments

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/13/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Disposition - Follow-Up

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551092**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Injection Site Pain	Aug/24/2020 17:00	NO End Date Time: Aug/26/2020 08:00	Repeating Pages
2.	ADVERSE EVENT	2	Injection site pain	Sep/15/2020 17:00	NO End Date Time: Sep/17/2020 17:00	Repeating Pages
3.	ADVERSE EVENT	3	Headache	Sep/16/2020 08:00	NO End Date Time: Sep/16/2020 10:00	Repeating Pages
4.	ADVERSE EVENT	4	Exposure during pregnancy	Feb/3/2021 UNK:UNK	YES	Repeating Pages

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection Site Pain]
4.	Start Date Time:	Aug/24/2020 17:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/26/2020 08:00
6.	Toxicity Grade:	1

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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
12.	Was a Non-Drug Treatment given?	NO

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Sep/15/2020 17:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/17/2020 17:00
6.	Toxicity Grade:	1

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Sep/16/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 10:00
6.	Toxicity Grade:	1

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[4]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure during pregnancy]	
4.	Start Date Time:	Feb/3/2021 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: [sexual intercourse]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Medication Error

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flu vaccine	Oct/14/2020	Repeating Pages

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flu vaccine]
5.	Date:	Oct/14/2020

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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?	

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

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

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551092**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT

Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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
----	-----------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Mar/11/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/13/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-12-2021 14:14:35 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-24-2020 14:28:20 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-24-2020 14:32:53 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable <hr/> Not Applicable

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
6	Mar-11-2021 15:34:34 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable <hr/> Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-12-2021 14:14:35 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Julie Glazier	N/A	Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Mar-12-2021 09:54:26 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Julie Glazier	N/A	Mar-11-2021 15:30:59 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Oct-21-2020 16:48:44 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-24-2020 14:24:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 14:24:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-24-2020 14:24:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: OBTAINED Date Written Consent Obtained Aug/24/2020	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-24-2020 14:24:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10551092	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:24:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1972	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-24-2020 14:24:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-24-2020 14:24:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-24-2020 14:24:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: WHITE	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-24-2020 14:28:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/24/2020	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-24-2020 14:28:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-24-2020 14:28:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-24-2020 14:28:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/24/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 70.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-24-2020 16:43:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 174.5	Transcription Error
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 189.2	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-24-2020 16:43:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23.0	Transcription Error
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19.6	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

& Canada)

7.a

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location:: HEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 36.5	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

7.a Unit:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-24-2020 14:30:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/24/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 61282	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 08:09:31 (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-25-2020 08:09:31 (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-25-2020 08:09:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 08:09:31 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 08:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 08:09:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RT D: V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:09:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RTV	Initial Entry

5.b

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-25-2020 08:09:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RT D: W	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:09:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RTW	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-25-2020 08:09:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RT D: X	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:09:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RTX	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-25-2020 08:10:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPFTY D: P	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:10:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFTYP	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-25-2020 08:10:10	ACV0PFEINFP6000	Megan Pastores	Data Entry: Sample I BPFTY	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		(pfe.mpastores)	D: R	
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFTYR	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 07:56:09 (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-25-2020 07:56:09 (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-25-2020 07:56:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 07:56:09 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 07:56:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 07:56:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RT D: N	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 07:56:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RTN	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (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-24-2020 14:30:57 (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
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/24/2020 11:38	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (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-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-24-2020 14:31:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO - REACTOGENI CITY E-DIARY NO T COLLECTED FO R THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-16-2020 08:39:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/15/2020	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551092

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Sep-16-2020 08:39:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/15/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-16-2020 08:39:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location: 36.9 C FORE HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 08:39:56 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 1	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-16-2020 08:39:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 36.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 08:39:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-16-2020 08:39:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: FOREHEAD	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 09:07:27 (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-16-2020 09:07:27 (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-16-2020 09:07:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 09:07:27 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 09:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 09:07:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP922 D: D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 09:07:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP922D	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (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-16-2020 08:40:39 (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
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/15/2020 14:13	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (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-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 15:59:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Oct/13/2020	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-13-2020 15:23:24 (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-13-2020 15:23:24 (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-13-2020 15:23:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 15:23:24 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-13-2020 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Oct/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-13-2020 15:23:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BR2PB D: P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 15:23:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BR2PBP	Initial Entry

5.b

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-13-2020 15:23:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BR2PB D: R	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 15:23:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BR2PBR	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-13-2020 15:23:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BS89X D: 1	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 15:23:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BS89X1	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-13-2020 15:24:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BS89X D: 2	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 15:24:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BS89X2	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551092

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 15:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Mar/11/2021	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Mar-11-2021 15:53:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-11-2021 15:53:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-11-2021 15:56:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 15:53:49 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Mar-11-2021 15:53:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Mar/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-11-2021 15:56:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BR2P9 D: D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:56:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BR2P9D	Initial Entry

5.b

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-11-2021 15:56:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BSG7L D: S	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:56:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BSG7LS	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-11-2021 15:56:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BSG7L D: T	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:56:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BSG7LT	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-13-2020 15:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Oct/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-13-2020 15:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-13-2020 15:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (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
Sep-16-2020 08:44:47 (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
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Injection Site Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/24/2020 17:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO End Date Time: Aug/26/2020 08: 00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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).

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (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
Oct-13-2020 16:00:49 (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
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Injection site pain	Initial Entry

4. Start Date Time:

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/15/2020 17:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date Time: Sep/17/2020 17:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Generated Time (GMT): 29-Mar-2021 04:44

prevent above outcomes).

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (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
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Headache	Initial Entry

4. Start Date Time:

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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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/16/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date Time: Sep/16/2020 10:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

prevent above outcomes).

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

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Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (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-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Exposure during pregnancy	Initial Entry

4. Start Date Time:

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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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Feb/3/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-11-2021 15:34:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	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

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

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prevent above outcomes).

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RELATED If Not Related to stu dy treatment(s), this event is due to: OTHER <i>If Other, specify:</i> sexual intercour	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1055

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Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Mar-12-2021 20:06:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rose Madelein (pfe.rose19)	Query 1: Closed	Response satisfies query
Mar-12-2021 10:30:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	correct as entered per sponsor guidance
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Exposure during pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNKNOWN	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Flu vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Oct/14/2020	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 15:32:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Mar/11/2021	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Mar-11-2021 15:33:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 15:32:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Mar-11-2021 15:32:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Participant is willin g to return for Vacc ination 3 Participant is: eligible and NO T confirmed to h ave received onl y placebo at Vac	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

			ination 1/2	
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090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-11-2021 15:33:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Mar/11/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-11-2021 15:33:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-13-2020 15:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-24-2020 14:30:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-24-2020 14:28:38 (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-13-2020 15:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/13/2020	Initial Entry
Aug-24-2020 14:30:34	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/24/2020	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
Aug-24-2020 14:28:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/24/2020	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551092

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 15:20:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae408b\Final\Final On: 01-Apr-2021 05:41 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/24/2020
----	--------------	----------------------------------------------------------

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10551094]
2.	Birth Date:	(b) (6)/1964
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 _____
----	----------------------------------------	-------------------------

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/24/2020
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: 1055

Subject No: 10551094

Generated By: pfe.levisc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Dermatomyositis]
	Start Date:	UNK/UNK/1995
	Ongoing:	NO
		End Date: UNK/UNK/1998

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/24/2020
2.	Weight:	[75.4]
3.	Unit:	kg
4.	Height:	[167.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[35.9]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/24/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/24/2020
2.	Randomization Number:	[238378]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
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	[BP6RV3]
5.b	Sample ID	[BP6RV4]
5.c	Sample ID	[BP6RV5]
5.d	Sample ID	[BPFTYV]
5.e	Sample ID	[BPFTYW]

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
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	[BP6RTY]
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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/24/2020 12:32
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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/14/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[35.1]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

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

Lab Result

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/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	[BP9212]
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/14/2020 10:53
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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/12/2020
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551094**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/12/2020
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	[BPV0KK]
5.b	Sample ID	[BPV0KL]
5.c	Sample ID	[BS89WF]
5.d	Sample ID	[BS89WG]

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/10/2020
2.	Date of First Symptom Started:	Nov/8/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/12/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.a	Symptoms - Other Text:	[fatigue]

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551094**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Nov/10/2020
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	[CV00576]
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551094**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Health Care Utilization

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

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?	NO
----	----------------------------------------------------------------------	----

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Respiratory Treatment

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Category f or Lab Tes t	Vendor Nam e (DERIVED)	Collecti on Date :	Specim en Type	Lab Result			Form Instan ce
1.					Sponsor-Defi ned Identifie r	Te st:	Res ult:	Repeating Pages

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

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Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/22/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/22/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1055**Subject No:** 10551094**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2PLT]
5.b	Sample ID	[BS3B33]
5.c	Sample ID	[BS3B34]

Header Text: c4591001

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

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

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Disposition - Follow-Up

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

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Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Injection Site Pain	Sep/15/2020 UNK:UNK	NO End Date Time: Sep/16/2020 UNK :UNK	Repeating Pages
2.	ADVERSE EVENT	2	Headache	Sep/15/2020 UNK:UNK	NO End Date Time: Sep/16/2020 UNK :UNK	Repeating Pages
3.	ADVERSE EVENT	3	injection site soreness	Jan/22/2021 0 4:00	NO End Date Time: Jan/23/2021 06:00	Repeating Pages
4.	ADVERSE EVENT	4	Injection Site Pain	Feb/11/2021 16:00	NO End Date Time: Feb/13/2021 07:0 0	Repeating Pages
5.	ADVERSE EVENT	5	Headache	Feb/12/2021 06:00	NO End Date Time: Feb/13/2021 06:0 0	Repeating Pages

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
6.	ADVERSE EVENT	6	Left Axillary Adenopathy	Feb/12/2021 06:00	NO End Date Time: Feb/15/2021 06:00	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection Site Pain]
4.	Start Date Time:	Sep/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	1

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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
12.	Was a Non-Drug Treatment given?	NO

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Sep/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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
12.	Was a Non-Drug Treatment given?	NO

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site soreness]
4.	Start Date Time:	Jan/22/2021 04:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/23/2021 06:00
6.	Toxicity Grade:	1

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection Site Pain]
4.	Start Date Time:	Feb/11/2021 16:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/13/2021 07:00
6.	Toxicity Grade:	1

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Feb/12/2021 06:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/13/2021 06:00
6.	Toxicity Grade:	1

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	YES
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left Axillary Adenopathy]
4.	Start Date Time:	Feb/12/2021 06:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/15/2021 06:00
6.	Toxicity Grade:	1

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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	[]

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	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: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Medication Error

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Radiation Treatment

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

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

Vital Signs Details

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551094**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/15/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/20/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/21/2021
2.	Erroneous Visit	

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/21/2021
----	--------------	----------------------------------------------------------

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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 _____
----	----------------------------------------	-------------------------

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/21/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/21/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/21/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P2F]
5.b	Sample ID	[BS3B7W]
5.c	Sample ID	[BS3B7V]

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/21/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P2D]
-----	-----------	----------

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/21/2021 14:54
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/11/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P63]
-----	-----------	----------

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/11/2021 12:04
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/11/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Mar/11/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/12/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-12-2021 14:16:22 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-24-2020 14:43:35 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
6	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
7	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
8	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
9	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-21-2021 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-12-2021 14:16:22 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Megan Pastores	N/A	Mar-12-2021 11:40:58 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-17-2021 15:58:13 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** Investigator Signature -
Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature
History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551094**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**Affidavit:**

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Feb-17-2021 12:09:26 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-12-2021 15:45:23 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Elle Billman	N/A	Feb-11-2021 14:39:40 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-11-2021 14:26:33 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Feb-11-2021 13:08:40 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-25-2021 12:09:49 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
 Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
 History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

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

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

Elle Billman	N/A	Jan-25-2021 11:32:28 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-21-2021 18:29:27 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Elle Billman	N/A	Jan-21-2021 15:18:23 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-20-2021 17:02:55 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Dec-22-2020 15:46:32 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Nov-13-2020 10:53:55 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
 Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
 History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Nov-12-2020 15:16:55 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Nov-10-2020 13:26:41 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Elle Billman	N/A	Nov-10-2020 12:38:02 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Oct-21-2020 16:49:36 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-24-2020 14:42:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 14:42:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-24-2020 14:42:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: OBTAINED Date Written Consent Obtained Aug/24/2020	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-24-2020 14:42:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10551094	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:42:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1964	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-24-2020 14:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-24-2020 14:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-24-2020 14:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: WHITE	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-24-2020 14:43:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-24-2020 14:43:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-24-2020 14:43:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-24-2020 14:43:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551094**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)***1.a***

Date	Location	User	Value	Reason
Aug-24-2020 14:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical H Dermatom istory Ter yositis m: Start Date UNK/UN : K/1995 Ongoing: NO End Date : UNK/U NK/199 8	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 14:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-24-2020 14:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Dermatomyositis	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/1995	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-24-2020 14:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date: UNK/UNK/1998	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/24/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 75.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 167.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier: 1 Temperature: 35.9	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

			Temperatur C e Unit: Temperatur FORE e Location:: HEAD	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-25-2020 01:05:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Closed	As per site confirmation
Aug-24-2020 14:44:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	Original value is correct
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 35.9 C is outside of Normal Range

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

& Canada)				36.1 - 37.5 C.
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 35.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/24/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
-------------------------------------------------------------------------	-----------------	-------------------------	----------------------------------	---------------

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NEGATIVE	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-24-2020 14:45:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/24/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-24-2020 14:45:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 238378	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 08:11:51 (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-25-2020 08:11:51 (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-25-2020 08:12:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 08:11:51 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 08:11:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 08:12:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RV D: 3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:12:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RV3	Initial Entry

5.b

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-25-2020 08:12:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RV D: 4	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:12:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RV4	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-25-2020 08:12:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RV D: 5	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:12:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RV5	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-25-2020 08:14:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPFTY D: V	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:14:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFTYV	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-25-2020 08:14:24	ACV0PFEINFP6000	Megan Pastores	Data Entry: Sample I BPFTY	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		(pfe.mpastores)	D:	W	
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:14:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFTYW	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 07:56:57 (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-25-2020 07:56:57 (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-25-2020 07:57:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 07:56:57 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 07:56:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 07:57:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RT D: Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 07:57:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RTY	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (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-24-2020 14:45:37 (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
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/24/2020 12:32	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (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-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-24-2020 14:45:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO - REACTOGENI CITY E-DIARY NO T COLLECTED FO R THIS SUBJECT	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-14-2020 12:03:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/14/2020	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/14/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Record Identifier:: Temperature: 35.1 Temperature Unit: Temperature Location: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 1	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-15-2020 23:39:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 2: Closed	Response satisfies query
Sep-15-2020 10:10:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Answered	not clinically significant
Sep-15-2020 01:27:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 2: Opened	DM :Kindly confirm the temperature 35.1 C recorded is clinically significant or not, thank you.
Sep-15-2020 01:26:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Closed	DM :Kindly confirm the temperature 35.1 C recorded is clinically significant or not, thank you.

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-14-2020 12:06:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Query 1: Answered	Original value is correct
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 35.1 C is outside of Normal Range 36.1 - 37.5 C.
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 35.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/14/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NEGATIVE	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-14-2020 15:39:26 (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-14-2020 15:39:26 (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-14-2020 15:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-14-2020 15:39:26 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-14-2020 15:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Sep/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-14-2020 15:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP9212	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-14-2020 15:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP9212	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (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-14-2020 12:11:11 (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
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/14/2020 10:53	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------------------	-----------------------------------------	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (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-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551094

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-12-2020 13:10:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Oct/12/2020	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-12-2020 16:02:04 (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-12-2020 16:02:04 (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-12-2020 16:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020 16:02:04 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-12-2020 16:02:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Oct/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 16:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPV0K D: K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPV0KK	Initial Entry

5.b

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-12-2020 16:02:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPV0K D: L	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:02:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPV0KL	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-12-2020 16:02:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BS89W D: F	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:02:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BS89WF	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-12-2020 16:02:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BS89W D: G	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:02:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BS89WG	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-10-2020 12:40:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-10-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-10-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

				Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-10-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Nov/10/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form Version: 10-Oct-2020 16:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Nov/10/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Nov/8/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-25-2021 11:32:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO Date of Last Sym ptom Resolved: Nov/12/2020	New Information
Nov-10-2020 12:38:43	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00)
Pacific Time (US
& Canada)

4.a

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Symptoms: FEV ER Symptom Pr NO esent:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

4.b

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sympt NEW OR I oms: NCREASE D COUGH Sympt NO om Pr esent:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NEW OR INCREAS ED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-10-2020	ACV0PFEINFP6000	Elle Billman	Data Entry:	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

12:38:43 (UTC-08:00) Pacific Time (US & Canada)		(pfe.ebillman)	Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	
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4.c Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Symptoms: CHIL	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)			LS Symptom Present: NO	
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4.d Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

			Symp tom P resent :	
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4.e Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NEW OR INCREAS ED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sympt NEW LOSS oms: OF TASTE OR SMELL	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

			Symptom Present:	
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4.f Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

			Symp tom P resent :	
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4.g Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NEW OR INCREAS ED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Symptoms DIARR : HEA Symptom NO Present:	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Symptoms VOMI : TING Symptom NO Present:	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-10-2020 12:38:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Symptoms - fatigue Other: ue	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:57	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: fatigue	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form Version: 10-Oct-2020 16:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.lewissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form Version: 06-Jul-2020 21:54

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry
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5. Device Type:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Not Applicable	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Nov-10-2020 12:40:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-10-2020 12:40:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-12-2020 15:16:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-11-2020 07:33:25 (UTC-08:00)	ACV0PFEINFP6000	Carrie Nedrick (pfe.nedricke)	Query 1: Opened	DM: 'Sample Collected?' is Yes, however

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551094**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Nov-10-2020 12:40:34 (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.
Nov-10-2020 12:40:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection : Nov/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-12-2020 15:16:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample I CV0057 D: 6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Nov-12-2020 15:16:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: CV00576	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Nov-10-2020 12:40:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-10-2020 12:40:50 (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
Nov-10-2020 12:40:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Nov-10-2020 12:40:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Telehealth visit	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form Version: 10-Oct-2020 15:59

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1.a

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Type of Prac SPEC itioner: IALI ST Occurrence NO of Visits or Contacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

1.b

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Type of Pr EMER actitioner: GENC Y ROO M Occurrence NO e of Visits or Contact s:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: EMERGENCY RO OM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

1.c

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Type of P PRIMAR ractition Y CARE er: PHYSIC IAN Occurre NO nce of Vi sits or Co ntacts:	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: PRIMARY CARE P HYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Type of Practitioner: URGE NT C ARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Type of Practitioner: TELEPH ONE CO	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)			er: NSULTA TION	
			Occurre nce of Vi sits or Co ntacts:	

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: TELEPHONE CON SULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Type of Practi OT tioner: HE R	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

& Canada)			Occurrence of NO Visits or Cont acts:	
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Nov/10/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID- 19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-10-2020 12:41:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: 1	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/22/2020

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-22-2020 15:46:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Dec/22/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-22-2020 15:46:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/22/2020

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Dec-22-2020 15:54:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 15:54:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-22-2020 15:54:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 15:54:44 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/22/2020

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 15:54:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection : Dec/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 15:54:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BR2PL : T	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 15:54:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2PLT	Initial Entry

5.b

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/22/2020

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Dec-22-2020 15:55:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BS3B3 : 3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 15:55:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BS3B33	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-22-2020 15:56:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BS3B3 : 4	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Dec/22/2020

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 15:56:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BS3B34	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-12-2020 13:10:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Oct/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-12-2020 13:10:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-12-2020 13:10:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: COMPLETED	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (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
Oct-12-2020 13:16:16 (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
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Injection Site Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/15/2020 UNK: UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO End Date Time: Sep/16/2020 UN K:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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).

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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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

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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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (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
Oct-12-2020 13:27:54 (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
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Headache	Initial Entry

4. Start Date Time:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/15/2020 UNK: UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO End Date Time: Sep/16/2020 UN K:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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

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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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT APPLICABL E	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RECOVERED/RES OLVED	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (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
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: injection site sorenes s	Initial Entry

4. Start Date Time:

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-17-2021 12:09:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/22/2021 04:00	Transcription Error
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/22/2021 16:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO End Date Time: Jan/23/2021 06:0 0	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: 1	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RELATED	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

& Canada)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RECOVERED/RES OLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (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-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Injection Site Pain	Initial Entry

4. Start Date Time:

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Feb/11/2021 16:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO End Date Time: Feb/13/2021 07: 00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT APPLICABL E	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------------------	------------------------------------------	---------------

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RECOVERED/RES OLVED	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (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-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Headache	Initial Entry

4. Start Date Time:

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Feb/12/2021 06:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO End Date Time: Feb/13/2021 06:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT APPLICABL E	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RECOVERED/RES OLVED	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (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-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Left Axillary Adeno pathy	Initial Entry

4. Start Date Time:

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Feb/12/2021 06:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO End Date Time: Feb/15/2021 06: 00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT APPLICABL E	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RECOVERED/RES OLVED	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 14:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/15/2021	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Jan-20-2021 14:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 14:55:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-20-2021 14:55:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Participant is willi ng to return for Va ccination 3 Participant is: eligible per loca l/national reco mmendations a nd confirmed to	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:44

			have received o nly placebo at V accination 1/2	
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-20-2021 14:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/20/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-20-2021 14:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITIO NAL VACCINATIO N	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-21-2021 15:18:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/21/2021	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Jan-21-2021 15:18:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: OBTAINED Date Written Consent Obtained Jan/21/2021	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-21-2021 15:18:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/21/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-21-2021 15:18:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-21-2021 15:18:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: COMPLETED	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/21/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NEGATIVE	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Jan-21-2021 15:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-21-2021 15:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-21-2021 15:20:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 15:19:41 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-21-2021 15:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection : Jan/21/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-21-2021 15:20:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BR2P2 : F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 15:20:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2P2F	Initial Entry

5.b

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-21-2021 15:20:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample I BS3B7 D: W	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 15:20:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BS3B7W	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-21-2021 15:20:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BS3B7 : V	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 15:20:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BS3B7V	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Jan-21-2021 15:19:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-21-2021 15:19:14 (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
Jan-21-2021 15:19:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 15:19:14 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-21-2021 15:19:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection : Jan/21/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-21-2021 15:19:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BR2P2 : D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 15:19:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2P2D	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551094

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (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
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/21/2021 14:54	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (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
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-11-2021 13:08:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/11/2021	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/11/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NEGATIVE	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Feb-11-2021 14:39:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-11-2021 14:39:40 (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
Feb-11-2021 14:39:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 14:39:40 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 14:39:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection : Feb/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-11-2021 14:39:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BR2P6 : 3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 14:39:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2P63	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (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
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/11/2021 12:04	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------------	-----------------------------------------	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (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
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
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090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551094

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 11:40:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Mar/11/2021	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-12-2021 11:41:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Contact: Mar/11/2021	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-12-2021 11:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Mar/11/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREAT MENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: COMPLETED	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-12-2020 13:10:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-24-2020 14:45:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-24-2020 14:43:52 (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-12-2020 13:10:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/12/2020	Initial Entry
Aug-24-2020 14:45:13	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/24/2020	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
Aug-24-2020 14:43:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/24/2020	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551094

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 15:23:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae408a\Final\Final On: 01-Apr-2021 05:41 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/27/2020
----	--------------	----------------------------------------------------------

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10551128]
2.	Birth Date:	(b) (6)/1994
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN WHITE
6.	Racial Designation:	

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/27/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 _____
----	----------------------------------------	-------------------------

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/27/2020
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: 1055

Subject No: 10551128

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Form Comments

Medical History Details

1.	Line/MH Number:	Not Applicable _____ []
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	Not Applicable _____ []
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/27/2020
2.	Weight:	[120.2]
3.	Unit:	kg
4.	Height:	[174.5]
5.	Unit:	cm
6.	Body Mass Index:	[39.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/27/2020
2.	Randomization Number:	[69060]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/27/2020
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	[BP6RZX]
5.b	Sample ID	[BP6RZY]
5.c	Sample ID	[BP6RZZ]
5.d	Sample ID	[BPFV13]
5.e	Sample ID	[BPFV14]

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/27/2020
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	[BP6RZP]
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090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/27/2020 13:05
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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/17/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/17/2020
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	[BPV07H]
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090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/17/2020 10:59
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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/15/2020
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	[BR2PCX]
5.b	Sample ID	[BS89YC]
5.c	Sample ID	[BS89YD]

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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 Version: 20-Feb-2021 02:17

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551128**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**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:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551128**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	
----	----------------------------------------------------------------------	--

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

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

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

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/15/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Disposition - Follow-Up

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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551128**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	injection site pain	Jan/18/2021 09:47	NO End Date Time: Jan/21/2021 UNK:UNK	Repeating Pages

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site pain]
4.	Start Date Time:	Jan/18/2021 09:47
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/21/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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
12.	Was a Non-Drug Treatment given?	NO

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	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: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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	[]

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flu Vaccination	Sep/21/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flu Vaccination]
5.	Date:	Sep/21/2020

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Radiation Treatment

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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

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

Vital Signs Details

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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/6/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/13/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/18/2021
----	--------------	----------------------------------------------------------

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/18/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BS3B6P]
5.b	Sample ID	[BS3B6R]
5.c	Sample ID	[BR2P19]

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551128**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P17]
5.b	Sample ID	[]

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/18/2021 09:46
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/8/2021
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551128**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P5C]
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Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/8/2021 09:31
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/15/2020

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-09-2021 09:47:57 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-27-2020 14:55:21 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable <hr/> Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-27-2020 14:58:37 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable <hr/> Not Applicable

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-18-2021 10:40:39 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-09-2021 09:47:57 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Feb-08-2021 11:39:18 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-20-2021 17:20:59 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
 Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
 History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Jan-18-2021 10:39:32 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Nov-30-2020 14:20:09 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Megan Pastores	N/A	Nov-30-2020 11:58:28 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Oct-21-2020 17:02:19 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-27-2020 14:54:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 14:54:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Consent Was:

Date	Location	User	Value	Reason
Aug-27-2020 14:54:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: OBTAINED Date Written Consent Obtained Aug/27/2020	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-27-2020 14:54:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10551128	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-27-2020 14:54:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1994	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-27-2020 14:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: HISPANIC OR LATI NO(A) OR OF SPAN ISH ORIGIN	Initial Entry
-------------------------------------------------------------------------	-----------------	---------------------------------	--------------------------------------------------------------------------	---------------

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

Date	Location	User	Value	Reason
Nov-30-2020 11:58:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BLACK OR AFR ICAN AMERICA N WHITE	Transcription Error
Aug-27-2020 14:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: WHITE	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-27-2020 14:55:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/27/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-27-2020 14:55:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/27/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 120.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 174.5	Initial Entry
-------------------------------------------------------------------------	-----------------	---------------------------------	-----------------------------	---------------

5. Unit:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 39.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier: 1 Temperature: 36.6	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

			Temperatur C e Unit: Temperatur FORE e Location:: HEAD	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-27-2020 14:56:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/27/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-27-2020 14:56:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 69060	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 09:03:16 (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-28-2020 09:03:16 (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-28-2020 09:04:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 09:03:16 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 09:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Aug/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 09:04:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RZ D: X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 09:04:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RZX	Initial Entry

5.b

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-28-2020 09:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RZ D: Y	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 09:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RZY	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 09:04:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6RZ D: Z	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 09:04:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6RZZ	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-28-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPFV1 D: 3	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFV13	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-28-2020 09:05:26	ACV0PFEINFP6000	Megan Pastores	Data Entry: Sample I BPFV1	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		(pfe.mpastores)	D: 4	
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 09:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFV14	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-27-2020 16:58:38 (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-27-2020 16:58:38 (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-27-2020 16:58:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 16:58:38 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-27-2020 16:58:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Aug/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 16:58:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID BP6RZ : P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 16:58:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6RZP	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (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-27-2020 14:56:22 (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
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090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/27/2020 13:05	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (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-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-27-2020 14:56:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO - REACTOGENI CITY E-DIARY NO T COLLECTED FO R THIS SUBJECT	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551128

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-17-2020 11:58:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/17/2020	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Sep-17-2020 11:59:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/17/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-17-2020 11:59:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location: 36.7 C FORE HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-17-2020 11:59:34 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 1	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-17-2020 11:59:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 36.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-17-2020 11:59:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-17-2020 11:59:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: FOREHEAD	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-17-2020 14:19:16 (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-17-2020 14:19:16 (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-17-2020 14:19:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 14:19:16 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-17-2020 14:19:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Sep/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 14:19:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPV07 D: H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 14:19:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPV07H	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (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-17-2020 12:00:00 (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
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090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/17/2020 10:59	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (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-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 14:13:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Oct/15/2020	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-15-2020 15:29:25 (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 15:29:25 (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 15:29:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 15:29:25 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 15:29:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Oct/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 15:29:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BR2PC D: X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:29:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BR2PCX	Initial Entry

5.b

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-15-2020 15:29:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BS89Y D: C	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:29:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BS89YC	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 15:30:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BS89Y D: D	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:30:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BS89YD	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-15-2020 14:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Oct/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-15-2020 14:13:36 (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 14:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: COMPLETED	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (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
Feb-08-2021 11:41:31 (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
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/18/2021 09:47	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO End Date Time: Jan/21/2021 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	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).

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-15-2020 15:11:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-15-2020 15:11:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-15-2020 15:11:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-15-2020 15:11:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-15-2020 15:11:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Flu Vaccination	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-15-2020 15:11:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/21/2020	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-18-2021 10:39:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/6/2021	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Jan-18-2021 10:40:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 10:39:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-18-2021 10:39:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Participant is willi ng to return for Va ccination 3 Participant is: eligible per loca l/national reco mmendations a nd confirmed to	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

			have received o nly placebo at V accination 1/2	
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-18-2021 10:40:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/13/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-18-2021 10:40:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITIO NAL VACCINATIO N	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-18-2021 10:40:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/18/2021	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-18-2021 10:40:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: OBTAINED Date Written Consent Obtained Jan/18/2021	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-18-2021 10:40:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/18/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-18-2021 10:40:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-18-2021 10:40:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: COMPLETED	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-18-2021 14:50:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-18-2021 14:50:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-18-2021 14:50:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 14:50:20 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-18-2021 14:50:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection : Jan/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-18-2021 14:50:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BS3B6 : P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 14:50:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BS3B6P	Initial Entry

5.b

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-18-2021 14:50:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BS3B6 : R	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 14:50:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BS3B6R	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-18-2021 14:50:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BR2P1 : 9	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 14:50:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2P19	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-18-2021 14:49:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-18-2021 14:49:16 (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
Jan-18-2021 14:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 14:49:16 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-18-2021 14:49:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection : Jan/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-18-2021 14:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BR2P1 : 7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 14:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2P17	Initial Entry

5.b

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-18-2021 14:50:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID:	Transcription Error
Jan-18-2021 14:49:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample I BS3B6 D: P	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 14:50:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry:	Transcription Error
Jan-18-2021 14:49:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BS3B6P	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551128

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (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
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090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/18/2021 09:46	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (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
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00)
Pacific Time (US
& Canada)

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Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-08-2021 11:39:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/8/2021	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-08-2021 14:27:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-08-2021 14:27:09 (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
Feb-08-2021 14:27:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 14:27:09 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-08-2021 14:27:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection : Feb/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-08-2021 14:27:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BR2P5 : C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-08-2021 14:27:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2P5C	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (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
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090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/8/2021 09:31	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (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
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
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090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-15-2020 14:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-27-2020 14:56:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-27-2020 14:55:31 (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 14:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/15/2020	Initial Entry
Aug-27-2020 14:56:07	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/27/2020	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
Aug-27-2020 14:55:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/27/2020	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551128

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 15:32:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae407a\Final\Final On: 01-Apr-2021 05:41 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/28/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10551139]
2.	Birth Date:	(b) (6)/1967
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/28/2020
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: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	Dec/UNK/2016
	Ongoing:	YES

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/28/2020
2.	Weight:	[65.3]
3.	Unit:	kg
4.	Height:	[161.5]
5.	Unit:	cm
6.	Body Mass Index:	[25.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/28/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/28/2020
2.	Randomization Number:	[72367]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP6S18]
5.b	Sample ID	[BP6S19]
5.c	Sample ID	[BP6S1B]
5.d	Sample ID	[BPFV1S]
5.e	Sample ID	[BPFV1T]

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP6S15]
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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/28/2020 12:14
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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/17/2020
2.	Erroneous Visit	

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/17/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/17/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/17/2020
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	[BPV07R]
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/17/2020 14:21
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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/16/2020
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	[BR2PD3]
5.b	Sample ID	[BS89YR]
5.c	Sample ID	[BS89YP]

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551139**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	
----	----------------------------------------------------------------------	--

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Illness Details

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

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

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

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/16/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Disposition - Follow-Up

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	injection site soreness	Jan/20/2021 18:00	NO End Date Time: Jan/22/2021 08:00	Repeating Pages
2.	ADVERSE EVENT	2	chills	Jan/21/2021 14:00	NO End Date Time: Jan/22/2021 08:00	Repeating Pages

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site soreness]
4.	Start Date Time:	Jan/20/2021 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 08:00
6.	Toxicity Grade:	1

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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
12.	Was a Non-Drug Treatment given?	NO

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[chills]
4.	Start Date Time:	Jan/21/2021 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 08:00
6.	Toxicity Grade:	1

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Medication Error

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Influenza vaccine	Oct/14/2020	Repeating Pages

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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[eCRF Audit Trail History](#)

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza vaccine]
5.	Date:	Oct/14/2020

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[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?	

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

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

Vital Signs Details

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551139**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/13/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/18/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/20/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/20/2021
----	--------------	----------------------------------------------------------

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/20/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/20/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P22]
5.b	Sample ID	[BS3B7J]
5.c	Sample ID	[BS3B7H]

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P20]
-----	-----------	----------

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/20/2021 09:05
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/10/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P5T]
-----	-----------	----------

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/10/2021 09:16
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/16/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-10-2021 17:30:42 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-28-2020 13:14:35 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe.mpastores)	Not Applicable <hr/> Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA -
FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-20-2021 12:22:11 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-10-2021 17:30:42 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Feb-10-2021 10:12:08 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-20-2021 17:24:44 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Jan-18-2021 15:13:35 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Oct-21-2020 17:08:50 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-28-2020 13:12:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 13:12:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-28-2020 13:13:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: OBTAINED Date Written Cons ent Obtained Aug/28/2020	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-28-2020 13:12:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10551139	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-28-2020 13:12:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1967	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-28-2020 13:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-28-2020 13:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT HISPANIC O R LATINO(A) OR OF SPANISH ORI GIN	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------------------	---------------------------------------------------------------------------------	---------------

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

Date	Location	User	Value	Reason
Aug-28-2020 13:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: ASIAN	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551139

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-28-2020 13:14:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/28/2020	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-28-2020 13:15:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-28-2020 13:15:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-28-2020 13:15:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: COMPLETED	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551139**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)***1.a***

Date	Location	User	Value	Reason
Aug-28-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 1 Medical History Term: Hypertension Start Date: Dec/UNK/2016 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Hypertension	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

1.a Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Dec/UNK/2016	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/28/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 65.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 161.5	Initial Entry
----------------------------------------------------------------------	-----------------	-----------------------------------	-----------------------------	---------------

5. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Record Identifier: Temperature: 36.9	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

			Temperatu C re Unit: Temperatu FORE re Locatio HEA n:: D	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 36.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: C	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/28/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
-------------------------------------------------------------------------	-----------------	-------------------------	----------------------------------	---------------

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-28-2020 13:20:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/28/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-28-2020 13:20:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 72367	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 15:34:12 (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-28-2020 15:34:12 (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-28-2020 15:34:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 15:34:12 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 15:34:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 15:34:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6S1 D: 8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:34:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6S18	Initial Entry

5.b

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-28-2020 15:34:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6S1 D: 9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:34:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6S19	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 15:34:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6S1 D: B	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:34:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6S1B	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-30-2020 09:40:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BPFV1 D: S	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 09:40:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFV1S	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-30-2020 09:40:32	ACV0PFEINFP6000	Megan Pastores	Data Entry: Sample I BPFV1	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		(pfe.mpastores)	D: T	
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5.e Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 09:40:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPFV1T	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 15:24:02 (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-28-2020 15:24:02 (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-28-2020 15:24:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 15:24:02 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 15:24:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 15:24:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample I BP6S1 D: 5	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:24:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BP6S15	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (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-28-2020 13:21:47 (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
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/28/2020 12:14	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (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-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-28-2020 13:21:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO - REACTOGE NICITY E-DIARY NOT COLLECTED FOR THIS SUBJE CT	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-17-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/17/2020	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/17/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-17-2020 15:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier: Temperature: 36.5 Temperature Unit: Temperature Location: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

2.a Temperature:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 36.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/17/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-17-2020 15:14:01 (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-17-2020 15:14:01 (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-17-2020 15:14:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 15:14:01 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-17-2020 15:14:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Sep/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 15:14:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID BPV07 : R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 15:14:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPV07R	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-17-2020 15:11:13 (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-17-2020 15:11:13 (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
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 15:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/17/2020 14:21	Transcription Error
Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/17/2020 12:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-17-2020 15:11:13 (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-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-16-2020 12:23:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Oct/16/2020	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-16-2020 15:48:01 (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-16-2020 15:48:01 (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-16-2020 15:48:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-16-2020 15:48:01 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-16-2020 15:48:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 15:48:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID BR2PD : 3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 15:48:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BR2PD3	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055 Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:44

Oct-16-2020 15:48:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID BS89Y : R	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 15:48:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BS89YR	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-16-2020 15:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID BS89Y : P	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 15:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BS89YP	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-16-2020 12:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Oct/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-16-2020 12:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-16-2020 12:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (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
Feb-10-2021 10:13:56 (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
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: injection site sorenes s	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/20/2021 18:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO End Date Time: Jan/22/2021 08:0 0	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	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).

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT APPLICABLE	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (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
Feb-10-2021 10:15:04 (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
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: chills	Initial Entry

4. Start Date Time:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/21/2021 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO End Date Time: Jan/22/2021 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	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

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT APPLICABLE	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------------	--------------------------------------	---------------

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RECOVERED/RES OLVED	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-16-2020 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-16-2020 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-16-2020 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-16-2020 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-16-2020 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-16-2020 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Oct/14/2020	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-18-2021 15:13:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/13/2021	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Jan-18-2021 15:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 15:13:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-18-2021 15:13:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Participant is willi ng to return for Va ccination 3 Participant is: eligible per loca l/national reco mmendations a nd confirmed to	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

			have received o nly placebo at V accination 1/2	
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-18-2021 15:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/18/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-18-2021 15:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITIO NAL VACCINATIO N	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 12:21:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/20/2021	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: OBTAINED Date Written Consent Obtained Jan/20/2021	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-20-2021 12:22:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/20/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: COMPLETED	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/20/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Jan-20-2021 14:59:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 14:59:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 14:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 14:59:03 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-20-2021 14:59:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection : Jan/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 14:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BR2P2 : 2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 14:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2P22	Initial Entry

5.b

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-20-2021 14:59:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BS3B7 : J	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 14:59:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BS3B7J	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-20-2021 15:00:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BS3B7 : H	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 15:00:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BS3B7H	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Jan-20-2021 14:58:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 14:58:36 (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
Jan-20-2021 14:58:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 14:58:36 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-20-2021 14:58:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection : Jan/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 14:58:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BR2P2 : 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 14:58:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2P20	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551139

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (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
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Jan/20/2021 09:05	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (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
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-10-2021 10:12:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/10/2021	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/10/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
-------------------------------------------------------------------------	-----------------	-------------------------	----------------------------------	---------------

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-10-2021 15:06:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-10-2021 15:06:56 (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
Feb-10-2021 15:07:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 15:06:56 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-10-2021 15:06:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection : Feb/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-10-2021 15:07:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID BR2P5 : T	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 15:07:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2P5T	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (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
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/10/2021 09:16	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------------	-----------------------------------------	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (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
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
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090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-16-2020 12:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-28-2020 13:20:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-28-2020 13:15:21 (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-16-2020 12:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/16/2020	Initial Entry
Aug-28-2020 13:20:07	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/28/2020	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
Aug-28-2020 13:15:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Aug/28/2020	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551139

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 15:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae4076\Final\Final On: 01-Apr-2021 05:40 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/28/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10551145]
2.	Birth Date:	(b) (6)/1985
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/28/2020
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: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Form Comments

Medical History Details

1.	Line/MH Number:	Not Applicable _____ []
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____ []
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____ _____

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/28/2020
2.	Weight:	[89.0]
3.	Unit:	kg
4.	Height:	[166.0]
5.	Unit:	cm
6.	Body Mass Index:	[32.3]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/28/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/28/2020
2.	Randomization Number:	[73002]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP6S21]
5.b	Sample ID	[BP6S22]
5.c	Sample ID	[BP6S23]
5.d	Sample ID	[BPFV25]
5.e	Sample ID	[BPFV26]

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP6S1W]
-----	-----------	----------

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/28/2020 14:35
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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Sep/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/16/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Done //	Comments
4.	Laboratory Name and Address (Derived)	[]	
5.	Specimen Type:		

Lab Result

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Vaccination

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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	[BR2PCK]
5.b	Sample ID	[BR2PCL]
5.c	Sample ID	[BS89XX]
5.d	Sample ID	[BS89XY]

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Unplanned Assessments

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/14/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Dysphagia	Aug/UNK/2020 UNK:UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	Right upper extremity pain	Oct/10/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	Cerebral Capillary telangiectasia	Sep/26/2020 UNK:UNK	YES	Repeating Pages

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Dysphagia]	
4.	Start Date Time:	Aug/UNK/2020 UNK:UNK	Comments
5.	Is the adverse event still ongoing?	YES	
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, GI or neurological abnormality]	
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN	
11.	Was a Concomitant Medication given?	NO	

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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[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)	[Right upper extremity pain]
4.	Start Date Time:	Oct/10/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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: [Cause is being evaluated]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Cerebral Capillary telangiectasia]
4.	Start Date Time:	Sep/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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: [anatomical abnormality]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Medication Error

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

Lab Urinalysis

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

Lab Result

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/18/2021
2.	Erroneous Visit	

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible
----	-----------------------------------------------------------------------------------	----------------------------------------------------------------------------------

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/18/2021
2.	Primary Reason for Unblinding:	OTHER If other, specify: [Subject is not eligible due to medical issues. Wants to be unblinded to get vaccine elsewhere.]

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisc

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
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, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

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

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-25-2021 16:28:59 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Aug-28-2020 15:37:55 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Aug-28-2020 15:43:33 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Oct-13-2020 15:21:52 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	deferred as vaccine not administered Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
3	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
4	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
5	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
7	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
8	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
9	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
10	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
11	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable
			Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Oct-27-2020 16:44:04 (UTC-08:00) Pacific Time (US & Canada)	Lana Norman (pfe.lnorman)	no estimated start date can be provided other than late August

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-25-2021 16:28:59 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Feb-24-2021 11:19:23 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-22-2021 13:56:23 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
--------------	----------	-------------------------------------------------------------	------	--------

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Feb-22-2021 10:35:34 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
--------------	-----	-------------------------------------------------------------	--	-----------------------------------

Affidavit:

N/A

Helen Stacey	Approved	Oct-27-2020 16:54:08 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Status: Data Complete, Signed, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

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

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-28-2020 15:37:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 15:37:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Consent Was:

Date	Location	User	Value	Reason
Aug-28-2020 15:37:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: OBTAINED Date Written Consent Obtained Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject ID

Date	Location	User	Value	Reason
Aug-28-2020 15:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10551145	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-28-2020 15:36:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1985	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-28-2020 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-28-2020 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-28-2020 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: WHITE	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-28-2020 15:37:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-28-2020 15:38:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-28-2020 15:38:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-28-2020 15:38:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/28/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 89.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 166.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 32.3	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7.a

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier:: 1 Temperature: 36.6 Temperature Unit: C Temperature Location:: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551145**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/28/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-28-2020 15:40:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/28/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-28-2020 15:40:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 73002	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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 15:55:44 (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-28-2020 15:55:44 (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-28-2020 15:55:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 15:55:44 (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-28-2020 15:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 15:55:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Sample ID: BP6S21	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:55:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	<u>Data Entry:</u> BP6S21	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-28-2020 15:55:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	<u>Data Entry:</u> Sample ID: BP6S22	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:55:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	<u>Data Entry:</u> BP6S22	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 15:56:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	<u>Data Entry:</u> Sample ID: BP6S23	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:56:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	<u>Data Entry:</u> BP6S23	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-28-2020 15:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	<u>Data Entry:</u> Sample ID: BPFV25	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: BPFV25	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-28-2020 15:56:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Sample ID: BPFV26	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:56:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: BPFV26	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 15:58:15 (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-28-2020 15:58:15 (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-28-2020 15:58:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 15:58:15 (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-28-2020 15:58:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 15:58:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Sample ID: BP6S1W	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:58:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	<u>Data Entry:</u> BP6S1W	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (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-28-2020 15:40:36 (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-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/28/2020 14:35	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (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-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7. Route:

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (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-28-2020 15:40:36 (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-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-28-2020 15:40:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 15:20:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Deleted	Initial Entry
Oct-13-2020 15:20:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/16/2020	Initial Entry
Oct-10-2020 01:50:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe ks66)	Query 2: Reissued:Candidate	Visit 2 has not scheduled yet
Oct-09-2020 15:33:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 2: Answered	pending to be schedule as per PI discretion
Oct-08-2020 00:58:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe ks66)	Query 2: Reissued:Opened	DM 1: Visit 1 was on 28/Aug/2020, however visit 2 is not happened yet, please confirm when is visit 2 expected to occur.
Oct-07-2020 10:42:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Answered	visit has not occurred
Oct-05-2020 03:22:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe nairr29)	Query 2: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Vaccination, Vital Signs' forms at this visit. Thank you.
Oct-01-2020 14:12:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jarred E Lee (pfe.leej299)	Query 2: Candidate	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Vaccination, Vital Signs' forms at this visit. Thank you.

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Oct-01-2020 14:11:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jarred E Lee (pfe.leej299)	Query 1: Closed	Reissued under Candidate status due to visit has not occurred yet.
Sep-26-2020 03:30:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 1: Reissued:Opened	Kindly keep query in open status until visit is occurred. Thank you.
Sep-25-2020 12:25:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	visit has not occurred yet
Sep-24-2020 23:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Oct-13-2020 15:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/16/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-13-2020 15:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier:: 1 Temperature: 36.8 Temperature Unit: C Temperature Location:: FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-13-2020 15:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-13-2020 15:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 36.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-13-2020 15:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

2.a Temperature Location:

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-13-2020 15:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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3. Collection Date:

Date	Location	User	Value	Reason
Oct-13-2020 15:21:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-13-2020 15:22:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry
Oct-13-2020 15:21:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-13-2020 15:22:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-13-2020 15:21:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

6.a Not Done:

Date	Location	User	Value	Reason
Oct-13-2020 15:22:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT DONE	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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-13-2020 15:22:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-13-2020 15:22:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-13-2020 15:22:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 15:22:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: deferred as vaccine not administer ed	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewiss

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7. Route:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Not Applicable	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-14-2020 15:18:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Oct/14/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-14-2020 15:48:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-14-2020 15:48:53 (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-14-2020 15:49:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 15:48:53 (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.
Oct-14-2020 15:48:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-14-2020 15:49:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BR2PCK	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:49:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BR2PCK	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 15:49:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BR2PCL	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:49:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BR2PCL	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 15:49:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BS89XX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:49:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BS89XX	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-14-2020 15:49:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BS89XY	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:49:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BS89XY	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-14-2020 15:18:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-14-2020 15:18:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-22-2020 09:47:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Closed	Response satisfies query
Oct-22-2020 09:47:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 2: Closed	Response satisfies query
Oct-22-2020 08:31:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Answered	Changed data per query
Oct-22-2020 08:30:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Oct-22-2020 08:30:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Oct-22-2020 08:30:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: ADVERSE EVENT	Changed Information
Oct-21-2020 09:33:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Opened	Subject has not received vaccination 2, but status is entered as COMPLETED. Please verify and update accordingly, else clarify. Thank you.
Oct-14-2020 15:18:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: COMPLETED	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Form Created	

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (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
Sep-16-2020 13:19:49 (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
Sep-21-2020 04:18:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	to review again in line with start date update.
Sep-18-2020 08:57:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Query 1: Answered	Pending further evaluations
Sep-17-2020 08:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: There is no medical history entered for this subject. Please clarify if this remains correct or if any information has been obtained in the review of this event that may warrant updates.
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Dysphagia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1055**Subject No:** 10551145**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-28-2020 10:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	per site response
Oct-27-2020 16:43:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 1: Answered	no estimated start date can be provided other than late August
Oct-22-2020 13:42:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	CLINQUERY: Since V1 was on 28Aug20, please review if an estimate can be applied for the day in August that can be added into this field
Oct-22-2020 09:47:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	subject states late August, exact date unknown
Sep-21-2020 04:16:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	CLINQUERY: Please leave query in open state until further information obtained for start date.
Sep-18-2020 08:56:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Query 1: Answered	Pending further evaluations
Sep-17-2020 08:48:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: A complete start date for AEs is required. Per CRF guidelines, if an exact date is unknown please provide best estimate
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1055**Subject No:** 10551145**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-15-2020 12:07:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Oct-15-2020 10:04:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	still ongoing
Oct-14-2020 11:48:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Please review if this event 'Dysphagia' remains ongoing or if any update to the subject's condition/data can be applied to the CRF.
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 13:22:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER <i>If Other, specify:</i> unknown, GI or neurological abnormality	New Information
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-22-2020 08:31:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: DRUG WITHDRAWN	Changed Information
Sep-18-2020 13:42:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Query 1: Deleted	Initial Entry
Sep-18-2020 13:42:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT APPLICABLE	Initial Entry
Sep-18-2020 04:15:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 1: Reissued:Candidate	DM: Thank you for confirmation. Please consider responding this query only after data will be updated.
Sep-17-2020 14:48:49 (UTC-08:00) Pacific	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	pending further testing if 2nd

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)				vaccine will be given, temporary delay at this time
Sep-17-2020 05:10:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "Latest Action Taken with Study Treatment" is missing? kindly review and update.

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (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
Oct-14-2020 15:22:51 (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
Oct-15-2020 12:08:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Oct-15-2020 09:57:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-15-2020 09:57:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Right upper extremity pain	Changed Information
Oct-15-2020 07:20:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Please expand acronym (RUE) in order to permit coding
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RUE pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1055**Subject No:** 10551145**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Oct/10/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-02-2020 10:18:53 (UTC-08:00) Pacific	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	Response satisfies query

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1055**Subject No:** 10551145**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

Time (US & Canada)				
Nov-02-2020 09:49:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 2: Answered	still pending
Oct-28-2020 07:49:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Opened	CLINQUERY: Is there any update to this entry 'Cause is being evaluated' that can be added to the CRF?
Oct-16-2020 11:04:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhank01)	Query 1: Closed	Response satisfies query
Oct-15-2020 09:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Updated
Oct-15-2020 09:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Cause is being evaluated	Updated
Oct-15-2020 01:13:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rajashekhhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "Is this event related to study treatment" Is reported as 'Not Related', however response for, 'Please indicate what this event is due to' is missing. Kindly review and update.
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NOT RECOVERED/NOT RESO LVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: NO	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (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
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-19-2020 10:57:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Oct-19-2020 09:13:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-19-2020 09:13:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Cerebral Capillary telangiectasia	New Information
Oct-16-2020 22:33:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify CAPILLARY TELANGIECTASIA as follows...The term appears incomplete. If reporting CEREBRAL CAPILLARY TELANGIECTASIA,

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				update the verbatim term as such. Otherwise clarify and update the term as appropriate. Thank you.
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry : Capillary tel angiectasia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)

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
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-20-2020 05:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ankita Thakur (pfe.thakua20)	Query 1: Closed	Response satisfies query.
Oct-19-2020 09:13:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-19-2020 09:13:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: anatomical abnormality	New Information
Oct-19-2020 02:07:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "If Not Related to study treatment(s), this event is due to is reported as "Other", however specify is missing? kindly review and update.
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			OTHER	
--	--	--	-------	--

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-22-2021 10:35:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/18/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Feb-22-2021 10:37:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-22-2021 10:38:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/18/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-04-2021 23:53:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 2: Closed	Response satisfies query
Mar-04-2021 09:59:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Answered	Original value is correct
Feb-25-2021 22:02:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 2: Opened	IVRS Reconciliation: Other is selected as the primary reason for unblinding but matching blind break is not captured in IRT. Please correct primary reason in Inform or confirm as correct".
Feb-25-2021 00:57:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_35
Feb-24-2021 11:19:23 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Pacific Time (US & Canada)			d	
Feb-24-2021 11:19:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data</u> <u>Entry</u> : OTH ER <i>If ot her, spec ify:</i> Su bje ct i s n ot eli gib le du e t o me dic al i ssu es. Wa nts to be un bli nd ed to get va cci ne els ew her e.	Transcription Error

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

<p>Feb-24-2021 00:49:15 (UTC-08:00) Pacific Time (US & Canada)</p>	<p>ACV0PFEINFP6000.InFormAdapter.Discrepancy</p>	<p>DMW QUERY (pfe.DMW_QUERY)</p>	<p>Query 1: Op ened</p>	<p>DMW7390884;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.</p>
<p>Feb-22-2021 10:38:06 (UTC-08:00) Pacific Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Elle Billman (pfe.ebillman)</p>	<p><u>Data Entry</u> : ASSE SS EL IGIBI LITY FOR ADDI TION AL V ACCI NATI ON</p>	<p>Initial Entry</p>

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551145

Generated By: pfe.lewissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-22-2020 08:30:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Changed Information
Oct-14-2020 15:18:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-28-2020 15:40:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-28-2020 15:38:28 (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-22-2020 08:30:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Changed Information
Oct-14-2020 15:18:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry
Aug-28-2020 15:40:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/28/2020	Initial Entry
Aug-28-2020 15:38:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/28/2020	Initial Entry

090177e196ae4078\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-27-2020 13:01:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551153

Generated By: pfe.levissc

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/31/2020
----	--------------	----------------------------------------------------------

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10551153]
2.	Birth Date:	(b) (6)/1957
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/31/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551153

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/31/2020
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: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetic neuropathy]
	Start Date:	Feb/UNK/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Type 2 diabetes]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/31/2020
2.	Weight:	[68.8]
3.	Unit:	kg
4.	Height:	[173.8]
5.	Unit:	cm
6.	Body Mass Index:	[22.8]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.4]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/31/2020
2.	Randomization Number:	[247288]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
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	[BP6S3F]
5.b	Sample ID	[BP6S3G]
5.c	Sample ID	[BP6S3H]
5.d	Sample ID	[BPFV2P]
5.e	Sample ID	[BPFV2R]

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
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	[BP6S38]
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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/31/2020 13:30
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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551153

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/21/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[35.9]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
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	[BPV088]
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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/21/2020 12:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/19/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
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	[BR2PDS]
5.b	Sample ID	[BS8B02]
5.c	Sample ID	[BS8B01]

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** DATE OF VISIT - ILLNESS ONSET Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** HEALTH CARE UTILIZATION
Visit

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	
----	----------------------------------------------------------------------	--

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ILLNESS DETAILS
Visit

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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 Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Unplanned Assessments

1.	Assessments	
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/19/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.leviscc

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Perforated appendicitis	Aug/31/2020 19:00	NO End Date Time: Sep/16/2020 UNK: UNK	Repeating Pages
2. DELETED	ADVERSE EVENT	2	Appendicitis	Aug/UNK/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	Injection Site Pain	Aug/31/2020 18:00	NO End Date Time: Sep/3/2020 08:00	Repeating Pages
4.	ADVERSE EVENT	4	Injection site pain	Sep/22/2020 08:00	NO End Date Time: Sep/24/2020 08:00	Repeating Pages
5.	ADVERSE EVENT	5	Fatigue	Sep/21/2020 16:00	NO End Date Time: Sep/21/2020 20:00	Repeating Pages

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Perforated appendicitis]
4.	Start Date Time:	Aug/31/2020 19:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: [bacterial infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[2020342548]

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1055**Subject No:** 10551153**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Deleted, Frozen, Verified**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44***** THIS REPEATING FORM HAS BEEN DELETED *****

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[Form Audit Trail](#)

Adverse Event Report

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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: [possession of an appendix]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[]

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1055**Subject No:** 10551153**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection Site Pain]
4.	Start Date Time:	Aug/31/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/3/2020 08:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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	[]

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Sep/22/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/24/2020 08:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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	[]

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Sep/21/2020 16:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/21/2020 20:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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	[]

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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	[]

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.leviscc

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/19/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Oct-26-2020 15:26:11 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 30-Jul-2020 21:29
Site No: 1055
Subject No: 10551153
Generated By: pfe.levisse
Form: INCLUSION/EXCLUSION CRITERIA - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1055) Diablo Clinical Research Incorporated
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Aug-31-2020 15:06:01 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable <hr/> Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Oct-26-2020 15:26:11 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

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

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551153

Generated By: pfe.levissc

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-31-2020 15:05:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 15:05:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-31-2020 15:05:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: OBTAINED Date Written Consent Obtain ed Aug/31/2020	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-31-2020 15:05:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10551153	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:05:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1957	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-31-2020 15:05:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-31-2020 15:05:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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-31-2020 15:05:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: ASIAN	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-31-2020 15:05:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-31-2020 15:06:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I.a

Date	Location	User	Value	Reason
Aug-31-2020 15:09:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Diabetic neur Term: opathy Start Date: Feb/UNK/200 5 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:36 (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-31-2020 15:09:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Diabetic neuropathy	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Feb/UNK/2005	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:36	ACV0PFEINFP6000	Julie Glazier	Data Entry:	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1055
Subject No: 10551153
Generated By: pfe.levisse
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1055) Diablo Clinical Research Incorporated
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		(pfe.jglazier)	YES	
----------------------------------------	--	----------------	-----	--

<i>l.b</i>				
Date	Location	User	Value	Reason
Aug-31-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Hyperlipidemia Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1055
Subject No: 10551153
Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1055) Diablo Clinical Research Incorporated
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:58 (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-31-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Hyperlipidemia	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/2010	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-31-2020 15:10:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Hypertension Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:14 (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-31-2020 15:10:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Hypertension	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/2010	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-31-2020 15:10:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Type 2 diabetes Start Date: UNK/UNK/ 2005 Ongoing: YES	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:38 (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-31-2020 15:10:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Type 2 diabetes	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/2005	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551153

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 68.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 173.8	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22.8	Initial Entry
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7.a

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier: 1 : Temperature: 36.4 Temperature Unit C : Temperature Loc FOREHE ation:: AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 36.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-31-2020 15:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 247288	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-31-2020 16:05:57 (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-31-2020 16:05:57 (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-31-2020 16:06:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 16:05:57 (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-31-2020 16:05:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1055**Subject No:** 10551153**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

Aug-31-2020 16:06:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP6S3F	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 16:06:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6S3F	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-31-2020 16:06:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP6S3G	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 16:06:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6S3G	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-31-2020 16:06:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP6S3H	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 16:06:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6S3H	Initial Entry

5.d

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-31-2020 16:06:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPFV2P	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 16:06:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPFV2P	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-31-2020 16:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPFV2R	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 16:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPFV2R	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-31-2020 15:55:38 (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-31-2020 15:55:38 (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-31-2020 15:55:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 15:55:38 (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-31-2020 15:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Aug-31-2020 15:55:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP6S38	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 15:55:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP6S38	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551153

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (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-31-2020 15:07:21 (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-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/31/2020 13:30	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (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
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Aug-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------------------	----------------------------	---------------

7. Route:

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (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-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-31-2020 15:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-21-2020 12:59:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/21/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551153

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Sep-21-2020 14:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/21/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 14:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Record Identifier 1 :: Temperature: 35.9 Temperature Uni C t: Temperature Loc FOREHE ation:: AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 14:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-22-2020 05:07:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 1: Closed	Response satisfies query
Sep-21-2020 14:05:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Query 1: Answered	Original value is correct
Sep-21-2020 14:05:11 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 35.9 C is outside of

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)				Normal Range 36.1 - 37.5 C.
Sep-21-2020 14:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 35.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-21-2020 14:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-21-2020 14:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: FOREHEAD	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 12:59:14 (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-21-2020 12:59:14 (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-21-2020 12:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 12:59:14 (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-21-2020 12:59:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-21-2020 12:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPV088	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 12:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPV088	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551153

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (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-21-2020 14:07:00 (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 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/21/2020 12:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (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
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Sep-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (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-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 13:15:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Oct/19/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-19-2020 15:05:00 (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-19-2020 15:05:00 (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-19-2020 15:05:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 15:05:00 (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-19-2020 15:05:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Oct-19-2020 15:05:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BR2PDS	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 15:05:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BR2PDS	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 15:05:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BS8B02	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 15:05:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BS8B02	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 15:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BS8B01	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 15:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BS8B01	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-19-2020 13:15:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 13:15:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 13:15:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Sep-09-2020 13:12:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Deleted	deleted as requested
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Form Created	

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (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
Sep-04-2020 08:46:39 (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
Sep-16-2020 05:52:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	resolved
Sep-15-2020 10:27:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	term has been updated on form, will resend
Sep-11-2020 03:09:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020342548,the term in Safety database was updated to 'Appendicitis. Per PSSR, The SAE term reported on the SAE form is appendicitis. Please confirm correct term. If PERFORATED APPENDICITIS,please submit a follow-up SAE form.

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (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, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-10-2020 08:56:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Perforated appendicitis	Changed Information
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Perforated appendix	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Aug/31/2020 19:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-19-2020 13:29:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date Time: Sep/16/2020 UNK:UNK	New Information
Sep-22-2020 09:38:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Barialai Kakar (pfe.kakarb)	Query 2: Closed	Response satisfies query
Sep-15-2020 12:20:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Answered	source has been updated, still ongoing
Sep-15-2020 11:58:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sholeh Majdi-Yazdi (pfe.majdis01)	Query 2: Opened	Please confirm and amend. Per source (AE/SAE log) the stop date is 01Sep2020.
Sep-11-2020 08:34:29 (UTC-08:00) Pacific	ACV0PFEINFP6000	Nandini Cossons	Query 1: Closed	Response satisfies query

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Time (US & Canada)		(pfe.cossons_n)		
Sep-10-2020 08:56:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	still ongoing, subject still recovering
Sep-09-2020 09:48:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Opened	GPD CLINQUERY: Please confirm whether adverse event of perforated appendix is still ongoing.
Sep-08-2020 09:08:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Changed Information
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date Time: Sep/1/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Sep-07-2020 01:45:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

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Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Perforated appendix: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<p>Data Entry: YES</p> <p>Is this serious event associate d with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result i n death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result i n persistent or significant dis ability/incapacity?</p> <p>NO</p> <p>Is this serious event life threa tening?</p> <p>NO</p> <p>Other medically important se rious event</p> <p>NO</p>	Initial Entry

8. Is this adverse event the result of a study Medication Error?

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If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-14-2020 09:14:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Clos ed	Response satisfies query
Oct-13-2020 14:39:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 1: Ans wered	data correct as recorded... appendicitis is a bacterial infection of the appendix. This is not a separate AE.
Oct-12-2020 08:59:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Ope ned	"If not related to study treatment other" = bacterial infection. Any symptoms, AEs or other key data should be collected on the appropriate page. Please confirm if this should be an AE or medhx and update

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				accordingly. "[cefall01 SDQ=17106]"
Sep-10-2020 08:57:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RE- LATED D If Not Related to study treat- ment(s), thi s even t is du e to: OTHER <i>If Other , s pecific y:</i> b a c t e ri a l i n f e	Changed Information

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			c t i o n	
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> appended	Initial Entry

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-11-2020 19:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-09-2020 14:11:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-09-2020 14:11:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Data Entry: YES	Changed Information
Oct-08-2020 12:24:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL per SAE report, IV antibiotics were given for SAE; please review and update if required
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-11-2020 19:16:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-09-2020 14:12:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

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Oct-09-2020 14:12:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Data Entry: YES	Changed Information
Oct-08-2020 12:45:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Per SAE report, subject had an appendectomy on 01 Sep 2020. Please review this non-drug treatment, and update accordingly
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 13:29:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Oct-19-2020 13:29:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RECOVERED/RESO LVED	Changed Information
Oct-19-2020 13:29:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE Perforated appendicitis: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-22-2020 09:38:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Barialai Kakar (pfe.kakarb)	Query 3: Closed	Response satisfies query

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Sep-15-2020 12:20:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 3: Answered	still ongoing
Sep-15-2020 12:00:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sholeh Majdi-Yazdi (pfe.majdis01)	Query 3: Opened	Please confirm and amend. Per paper AE/SAE log, the event has been recovered/resolved.
Sep-09-2020 04:35:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	issue resolved
Sep-08-2020 09:08:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-08-2020 09:08:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Perforated appendix: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-08-2020 09:08:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-08-2020 09:08:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RECOVERING/RESOLVING	Changed Information
Sep-07-2020 01:53:21 (UTC-08:00)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020342548 ,outcome was reported as

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Pacific Time (US &
Canada)

RECOVERING/RESOLVING
in SAE form however,
recorded as
RECOVERED/RESOLVED
on AE CRF. Please confirm
correct outcome. If safety
update is required, please
submit a follow-up form.

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

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-07-2020 01:45:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020342548	Initial Entry

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Generated By: pfe.lewissc

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1. Category:

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (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
Sep-04-2020 08:48:26 (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
Sep-09-2020 13:25:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	Response satisfies query
Sep-09-2020 13:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	Changed data per query
Sep-09-2020 08:59:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	clinical-pls remove AE of 'appendicitis' as this is subsumed within AE of perforated appendix. Thank you
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Appendicitis	Initial Entry

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4. Start Date Time:

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> Aug/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> 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
Sep-04-2020 08:48:26	ACV0PFEINFP6000	Julie Glazier	<u>Data Entry:</u>	Initial Entry

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(UTC-08:00) Pacific
Time (US & Canada)

(pfe.jglazier) NO

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> possession of an appendix	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

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Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RECOVERED/NOT RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (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
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Injection Site Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Aug/31/2020 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO End Date Time: Sep/3/2020 08:00	Initial Entry

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (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
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-20-2020 12:30:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Oct-20-2020 11:04:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/22/2020 08:00	Transcription Error
Oct-20-2020 10:32:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-20-2020 10:32:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/21/2020 08:00	Transcription Error

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Oct-20-2020 08:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Start date of Injection Site Pain is reported prior to the study vaccination administration. Please review entries and amend as appropriate.
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/20/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date Time: Sep/24/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Oct-19-2020 13:16:57 (UTC-08:00) Pacific	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)

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
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RECOVERED/RESOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (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
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Fatigue	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/21/2020 16:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date Time: Sep/21/2020 20:00	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551153

Generated By: pfe.levisse

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject Status

Date	Location	User	Value	Reason
Oct-19-2020 13:15:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-31-2020 15:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-31-2020 15:06:17 (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-19-2020 13:15:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry
Aug-31-2020 15:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry
Aug-31-2020 15:06:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-26-2020 14:57:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Helen Stacey (pfe hstacey)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae408c\Final\Final On: 01-Apr-2021 05:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/3/2020
----	--------------	---------------------------------------------------------

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10551176]
2.	Birth Date:	(b) (6)/1970
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal allergies]
	Start Date:	Apr/1/1982
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Angina]
	Start Date:	Mar/24/2010
	Ongoing:	NO End Date: Feb/4/2016
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sinus tachycardia]
	Start Date:	Apr/1/2019
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	Oct/1/2000
	Ongoing:	YES

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertriglyceridemia]
	Start Date:	Apr/1/2010
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Type 2 diabetes]
	Start Date:	Feb/1/2020
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary vasospasm]
	Start Date:	Mar/24/2010
	Ongoing:	NO End Date: Feb/4/2016
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anomalous coronary artery]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary artery bypass graft]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Redo of coronary bypass graft with re-implantation RCA and "unroofing of LAD bridge"]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/3/2020
2.	Weight:	[104.3]
3.	Unit:	kg
4.	Height:	[170.0]
5.	Unit:	cm
6.	Body Mass Index:	[36.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/3/2020
2.	Randomization Number:	[80233]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP91X8]
5.b	Sample ID	[BP91X9]
5.c	Sample ID	[BPFTDK]
5.d	Sample ID	[BPFTDL]

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP91X4]
-----	-----------	----------

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/3/2020 12:14
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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/23/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/23/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPV091]
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/23/2020 10:18
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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2PFY]
5.b	Sample ID	[BS8B20]
5.c	Sample ID	[BS8B1Z]

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Unplanned Assessments

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/22/2020
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: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Dec/18/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	WITHDRAWAL BY SUBJECT
4.	Specify Status:	[subject withdrew from study prior to Subject receiving Covid-19 vaccine outside of study]

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still On going	Form Instance
1.	ADVERSE EVENT	1	Coronary vasospasm	Sep/25/2020 UNK:UNK	NO End Date Time: Sep/26/2020 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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)	[Coronary vasospasm]
4.	Start Date Time:	Sep/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/26/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
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: [underlying cardiac disease]

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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	[2020375789]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Medication Error

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATION S	NO	Influenza vaccine	Oct/9/2020	Repeating Pages
2. DELETED	2	VACCINATION S	NO	BNT162b2	Dec/18/2020	Repeating Pages
3. DELETED	3	VACCINATION S	NO	BNT162b2	Jan/8/2021	Repeating Pages

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza vaccine]
5.	Date:	Oct/9/2020

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Deleted, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Concomitant Medications

1.	What is the medication identifier?	[2]	
2.	Category:	VACCINATIONS	
3.	Concomitant Medications Pre-specified:	NO	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[BNT162b2]	Comments
5.	Date:	Dec/18/2020	Comments

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	[3]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[BNT162b2]
5.	Date:	Jan/8/2021

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Lab Urinalysis

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

Lab Result

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Informed Consent - Asymptomatic Surveillance

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

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/14/2020
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, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Informed Consent - Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	
----	-------------------------------------------	--

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/14/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Dec/18/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-22-2021 14:00:05 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Sep-03-2020 13:40:29 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Jan-13-2021 15:38:10 (UTC-08:00) Pacific Time (US & Canada)	Lana Norman (pfe.lnorman)	previously reported as Unspecified Covid-19 vaccine

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Item	Date	User	Comment
5	Jan-13-2021 15:38:45 (UTC-08:00) Pacific Time (US & Canada)	Lana Norman (pfe.lnorman)	
5	Jan-13-2021 15:24:59 (UTC-08:00) Pacific Time (US & Canada)	Lana Norman (pfe.lnorman)	Unknown

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-22-2021 14:00:05 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elissa OConnor	N/A	Feb-22-2021 10:18:30 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-17-2021 08:55:01 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elissa OConnor	N/A	Feb-16-2021 13:52:28 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-10-2021 17:31:57 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elissa OConnor	N/A	Feb-10-2021 14:08:53 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-27-2021 17:11:06 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elissa OConnor	N/A	Jan-27-2021 08:08:46 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-20-2021 17:59:33 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Julie Glazier	N/A	Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Helen Stacey	Approved	Dec-16-2020 15:53:26 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Dec-16-2020 09:57:18 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Helen Stacey	Approved	Oct-27-2020 16:56:33 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-03-2020 13:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-03-2020 13:39:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: OBTAINED Date Written Consent Obtained Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject ID

Date	Location	User	Value	Reason
Sep-03-2020 13:37:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10551176	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:37:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1970	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-03-2020 13:39:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-03-2020 13:39:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:39:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: WHITE	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 13:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-03-2020 13:40:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-03-2020 13:40:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-03-2020 13:40:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I.a

Date	Location	User	Value	Reason
Sep-03-2020 13:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Seasonal allergies Start Date: Apr/1/1982 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:49:07 (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
Sep-03-2020 13:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Seasonal allergies	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Apr/1/1982	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 13:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Sep-03-2020 13:50:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Angina Start Date: Mar/24/2010 Ongoing: NO End Date: Feb/4/2016	Initial Entry
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1055**Subject No:** 10551176**Generated By:** pfe.levisse**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44***I.b Line/MH Number:***

Date	Location	User	Value	Reason
Sep-03-2020 13:50:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 10:57:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Sep-30-2020 09:24:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	Changed data per query
Sep-29-2020 09:04:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL On review of SAE report: Coronary vasospasm, past Med Hx of coronary vasospasm (2010-6) and Anomalous coronary artery (CABG x2) were mentioned, yet do not appear in CRF. Please review for clinical relevance and update Med Hx as appropriate.
Sep-03-2020 13:50:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Angina	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:50:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Mar/24/2010	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Sep-03-2020 13:50:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date: Feb/4/2016	Initial Entry
-------------------------------------------------------------------	-----------------	---------------------------------	---------------------------------------------------------	---------------

I.c

Date	Location	User	Value	Reason
Sep-08-2020 11:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Line/MH Number: 3 Medical History Term: Sinus tachycardia Start Date: Apr/1/2019 Ongoing: YES	Changed Information
Sep-04-2020 08:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Line/MH Number: 3 : Medical History Term: Cardiac arrhythmia Start Date: Apr/1/2019 Ongoing: YES	Changed Information
Sep-03-2020 13:51:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Arrhythmia : Start Date: Apr/1/2019 Ongoing: YES	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:00 (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
Sep-08-2020 12:04:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Sep-08-2020 11:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-08-2020 11:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sinus tachycardia	Changed Information
Sep-04-2020 10:17:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	CLINQUERY: Thank you for the update. However, could you clarify if any other description can be offered for the cardiac arrhythmia
Sep-04-2020 08:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-04-2020 08:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Cardiac arrhythmia	Changed Information
Sep-04-2020 07:45:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Please review if a more descriptive term can be applied to describe the 'Arrhythmia' reported.
Sep-03-2020 13:51:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Arrhythmia	Initial Entry

I.c Start Date:

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-03-2020 13:51:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Apr/1/2019	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-03-2020 13:51:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term Hypertensio : n Start Date: Oct/1/2000 Ongoing: YES	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:16 (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
Sep-03-2020 13:51:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Hypertension	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Oct/1/2000	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-03-2020 13:51:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 5 : Medical History T Hypertriglycerid emia Start Date: Apr/1/2010 Ongoing: YES	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:42 (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
Sep-03-2020 13:51:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Hypertriglyceridemia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Apr/1/2010	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-03-2020 13:52:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Type 2 diabetes Start Date: Feb/1/2020 Ongoing: YES	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:52:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:52:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Type 2 diabetes	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:52:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Feb/1/2020	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 13:52:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-30-2020 09:20:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 : Medical History T Coronary vasosp erm: asm Start Date: Mar/24/2010 Ongoing: NO End Date: Feb/4/2016	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 09:20:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 09:20:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Coronary vasospasm	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 09:20:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Mar/24/2010	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 09:20:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date: Feb/4/2016	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-30-2020 09:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: Anomalous coronary artery Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 09:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 09:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Anomalous coronary artery	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I.h Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 09:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/2010	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 09:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Sep-30-2020 09:23:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Coronary artery bypass graft Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2010	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 09:23:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 09:23:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Coronary artery bypass graft	Initial Entry

I.i Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 09:23:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/2010	Initial Entry

I.i Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 09:23:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

I.j

Date	Location	User	Value	Reason
Sep-30-2020 09:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M H Num ber: Medica Redo of coronary bypass gr l Histor aft with re-implantation RC y Term: A and "unroofing of LAD b ridge" Start D UNK/UNK/2016 ate:	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Ongoing: NO End Date: UNK/UNK/2016	
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I.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 09:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 09:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Redo of coronary bypass graft with re-implantation RCA and "unroofing of LAD bridge"	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 09:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/2016	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 09:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date: UNK/UNK/2016	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/3/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 104.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 170.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 36.1	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7.a

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier:: 1 Temperature: 36.8 Temperature Unit: C Temperature Location:: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 36.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/3/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

			Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-03-2020 13:42:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/3/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:42:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 80233	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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 15:59:31 (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-03-2020 15:59:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 15:59:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 15:59:31 (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-03-2020 15:59:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 15:59:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP91X8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-03-2020 15:59:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP91X8	Initial Entry
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5.b

Date	Location	User	Value	Reason
Sep-03-2020 15:59:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP91X9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 15:59:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP91X9	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 15:59:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPFTDK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 15:59:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPFTDK	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-03-2020 16:00:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPFTDL	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:00:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPFTDL	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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 16:00:22 (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-03-2020 16:00:22 (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-03-2020 16:00:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:00:22 (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-03-2020 16:00:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:00:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP91X4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Sep-03-2020 16:00:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP91X4	Initial Entry
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (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-03-2020 13:42:27 (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-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/3/2020 12:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (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-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (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-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-03-2020 13:42:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-23-2020 11:37:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/23/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-23-2020 11:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier:: 1 Temperature: 36.5 Temperature Unit: C Temperature Locatio n:: FOREHEA D	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 36.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Sep-23-2020 11:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/23/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

			Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-23-2020 15:06:34 (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-23-2020 15:06:34 (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-23-2020 15:06:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 15:06:34 (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-23-2020 15:06:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: YES Date of Collection: Sep/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 15:06:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Sample ID: BPV091	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Sep-23-2020 15:06:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: BPV091	Initial Entry
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (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-23-2020 11:37:55 (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-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/23/2020 10:18	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (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-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

7. Route:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (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-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-22-2020 12:29:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Oct/22/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 14:42:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-22-2020 14:42:53 (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-22-2020 14:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 14:42:53 (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.
Oct-22-2020 14:42:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: YES Date of Collection: Oct/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 14:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Sample ID: BR2PFY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Oct-22-2020 14:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: BR2PFY	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-22-2020 14:43:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Sample ID: BS8B20	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 14:43:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: BS8B20	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-22-2020 14:43:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: Sample ID: BS8B1Z	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 14:43:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Data Entry: BS8B1Z	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-22-2020 12:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Oct/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-22-2020 12:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-22-2020 12:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1055**Subject No:** 10551176**Generated By:** pfe.levissc**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-27-2021 08:08:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Data Entry: Dec/18/2020	Changed Information
Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Dec/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-10-2021 14:33:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	Response satisfies query
Feb-10-2021 14:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Feb-10-2021 14:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Data Entry: WITHDRAWAL BY SUBJECT	Changed Information
Jan-27-2021 12:25:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Reissued:Opened	CLINQUERY: Thank you for clarifying, status can be amended to be WITHDRAWAL BY SUBJECT since subject is opting to receive vaccine off study
Jan-27-2021 08:09:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Query 2: Answered	subject was discontinued prior to outside vaccination so it is not a PD

Header Text: c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1055**Subject No:** 10551176**Generated By:** pfe.levissc**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

Jan-25-2021 07:21:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 2: Opened	CLINQUERY: Since subject received a non-study covid-19 vaccine prior to discontinuing from study, please amend status to reflect PROTOCOL DEVIATION
Jan-25-2021 04:00:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Candidate	CLINQUERY: Since subject received a non-study covid-19 vaccine prior to discontinuing from study, please amend status to reflect PROTOCOL DEVIATION
Dec-22-2020 13:28:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is NO LONGER MEETS ELIGIBILITY CRITERIA but "Specify Status" is missing.
Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO LONGER MEETS ELIGIBILITY CRITERIA	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Feb-22-2021 10:44:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	Response satisfies query
Feb-22-2021 10:18:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Feb-22-2021 10:18:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Data Entry: subject withdrew from study prior to Subject receiving Covid-19 vacci	Changed Information

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			ne outside of study	
Feb-21-2021 22:47:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 2: Opened	CLINQUERY: In line with prior clarification "subject was discontinued prior to outside vaccination so it is not a PD" - please review entry in this field that suggests vaccine was received prior to study end
Feb-19-2021 10:14:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Candidate	CLINQUERY: In line with prior clarification "subject was discontinued prior to outside vaccination so it is not a PD" - please review entry in this field that suggests vaccine was received prior to study end
Jan-14-2021 13:20:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	non-study vax page updated
Jan-13-2021 15:25:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 1: Answered	pending data from a subject
Jan-06-2021 10:10:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Please capture the non-study vaccine in the CONMED VAX page under LOGS tab.
Dec-22-2020 13:29:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Subject received Covid-19 vaccine outside of study	Changed Information
Dec-22-2020 13:28:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Subject received Covid-19 vaccine study outside of study	Initial Entry

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Subject No: 10551176

Generated By: pfe.levisse

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Form Status:

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Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

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Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

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1. Category:

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (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
Sep-28-2020 13:38:39 (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
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Coronary vasospasm	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO End Date Time: Sep/26/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-28-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 3	Initial Entry

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-27-2020 20:23:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Oct-27-2020 09:24:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Query 2: Answered	Form was updated and faxed over on 10/26. Form is being uploaded to Florence.
Oct-23-2020 17:19:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020375789] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Sep-29-2020 03:46:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Coronary vasospasm: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO	Initial Entry

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			<p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/in capacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
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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
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-28-2020 14:41:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> underlying cardiac disease	New Information

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Subject No: 10551176

Subject Initials: ---

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Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	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
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
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Sep-29-2020 03:46:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<u>Data Entry:</u> 2020375789	Initial Entry
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Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-22-2020 12:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

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Form Status:

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Site Name: (1055) Diablo Clinical Research Incorporated

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Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-10-2021 14:24:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Form Deleted	Changed Information
Jan-13-2021 15:24:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Form Created	

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Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Feb-16-2021 13:52:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Form Deleted	Removing per sponsor request
Jan-13-2021 15:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Form Created	

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-22-2020 12:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-22-2020 12:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-22-2020 12:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-22-2020 12:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-22-2020 12:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Oct/9/2020	Initial Entry

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-13-2021 15:24:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-13-2021 15:24:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-13-2021 15:24:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-10-2021 14:32:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Feb-10-2021 14:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Query 1: Answered	ok will remove. since subject discontinued prior to receiving non-study vaccines
Jan-28-2021 07:00:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Opened	CLINQUERY: Clarified at FUP page that subject discontinued from study prior to

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				receiving non-study vaccines. If correct, then these vaccines should not be captured in CRF as occurred post end of study
Jan-27-2021 12:31:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Candidate	CLINQUERY: Clarified at FUP page that subject discontinued from study prior to receiving non-study vaccines. If correct, then these vaccines should not be captured in CRF as occurred post end of study
Jan-13-2021 15:38:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	<u>Data Entry:</u> BNT162b2	Changed Information
Jan-13-2021 15:24:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	<u>Data Entry:</u> Unspecified Covid-19 vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	<u>Data Entry:</u> Dec/18/2020	Initial Entry
Jan-13-2021 15:38:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	<u>Data Entry:</u>	Initial Entry
Jan-13-2021 15:24:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	<u>Data Entry:</u> Unknown	Initial Entry

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-13-2021 15:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-16-2021 15:16:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Feb-16-2021 13:52:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Removing per sponsor request
Feb-10-2021 22:29:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Opened	CLINQUERY: Clarified at FUP page that subject discontinued from study prior to receiving non-study

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*** THIS REPEATING FORM HAS BEEN DELETED ***

				vaccines. If correct, then these vaccines should not be captured in CRF as occurred post end of study
Feb-10-2021 14:23:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Candidate	CLINQUERY: Clarified at FUP page that subject discontinued from study prior to receiving non-study vaccines. If correct, then these vaccines should not be captured in CRF as occurred post end of study
Jan-13-2021 15:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Data Entry: BNT162b2	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Jan-27-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Mina Francisco (pfe.francm73)	Query 1: Closed	Response satisfies query
Jan-27-2021 08:11:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Query 1: Answered	we got a query on the final disposition CRF saying to add the vaccinations to the med log. Please advise
Jan-27-2021 02:02:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloim (pfe.moloim)	Query 1: Reissued: Opened	DM: Thank you, please note that there cannot be a date that is after the date of disposition follow-up. Please update as appropriate.

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Jan-26-2021 14:44:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Ans wered	do you want the second vaccine removed then?
Jan-14-2021 17:41:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW6841692;'Start Date' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Jan-13-2021 15:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Data Entry : Jan/8/ 2021	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Dec-16-2020 09:57:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Dec/14/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-01-2021 06:11:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 3: Closed	guidance review being undertaken for subjects who never signed consent for V101
Jan-27-2021 12:27:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 3: Reissued:Opened	CLINQUERY: Understood - the page completion options below are to clarify in V101 folder that visit will not go ahead as planned. Pages need to be completed to finalise CRF
Jan-27-2021 08:15:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Query 3: Answered	Subject never came in for V101 that is why the pages are not completed. they were discontinued in the study before then.
Jan-20-2021 05:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 3: Opened	CLINQUERY: Please complete the pages in the V101/Vax 3 folder. Date can be the date of contact/date deemed no further vax. Disp screening = No Longer Meets Eligibility. Capture the eligibility criterion not met in the IE page.
Jan-12-2021 14:23:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	to review with updated guidelines
Jan-08-2021 09:38:55	ACV0PFEINFP6000	auto query	Query 2: Answered	Transcription Error

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001 Visit: Potential ReVax Initial Contact - Unscheduled Form Version: 10-Dec-2020 02:25 Site No: 1055 Subject No: 10551176 Generated By: pfe.levisse				
(UTC-08:00) Pacific Time (US & Canada)		(autoquery)		
Jan-08-2021 09:38:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Transcription Error
Jan-08-2021 03:58:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Reissued:Opened	CLINQUERY: Please clarify, was the subject's Rx arm unblinded before or after knowledge of receipt of non-study vaccine (and so was there intention to proceed with V101 on unblind)? This may alter data selections
Dec-29-2020 12:08:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-29-2020 12:08:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	New Information
Dec-23-2020 08:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Opened	CLINQUERY: FUP status states subject had received a vaccine outside of the study, which would mean subject was ineligible for any further vaccination on study. Please clarify discrepancy in this entry vs FUP page.
Dec-16-2020 09:58:28 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(US & Canada)				
Dec-16-2020 09:57:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-16-2020 09:57:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-16-2020 09:58:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Dec/14/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-16-2020 09:58:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: ASSESS ELIGIBILITY FOR ADDI TIONAL VACCINATION	Initial Entry

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1055**Subject No:** 10551176**Generated By:** pfe.levisse**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Feb-10-2021 14:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Changed Information
Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-22-2020 12:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-03-2020 13:42:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-03-2020 13:40:46 (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
Feb-10-2021 14:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/18/2020	Changed Information
Jan-27-2021 08:08:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/18/2020	Changed Information
Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/21/2020	Initial Entry
Oct-22-2020 12:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/22/2020	Initial Entry
Sep-03-2020 13:42:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry
Sep-03-2020 13:40:46 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551176

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(US & Canada)				
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551176

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Oct-27-2020 12:45:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae4077\Final\Final On: 01-Apr-2021 05:41 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/3/2020
----	--------------	---------------------------------------------------------

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10551182]
2.	Birth Date:	(b) (6)/1958
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:	

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal allergies]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/3/2020
2.	Weight:	[109.0]
3.	Unit:	kg
4.	Height:	[180.4]
5.	Unit:	cm
6.	Body Mass Index:	[33.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[37.1]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition

1.	Randomization Date :	Sep/3/2020
2.	Randomization Number:	[251860]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP91XX]
5.b	Sample ID	[BP91XY]
5.c	Sample ID	[BPFTF1]
5.d	Sample ID	[BPFTF2]

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP91XV]
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090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/3/2020 15:09
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

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/25/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/25/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/25/2020
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	[BPV0BF]
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090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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/25/2020 13:41
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

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/26/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/26/2020
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	[BR2PGK]
5.b	Sample ID	[BS8B38]
5.c	Sample ID	[BS8B37]

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	
----	----------------------------------------------------------------------	--

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/26/2020
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: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 - **Form:** DATE OF VISIT - REPEAT SWAB
New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Melanoma	Nov/16/2020 UNK:UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	skin lesion of scalp	Sep/25/2020 10:00	NO End Date Time: Nov/16/2020 UNK:UNK	Repeating Pages

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Melanoma]
4.	Start Date Time:	Nov/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: [Sun exposure]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[2021036886]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[skin lesion of scalp]
4.	Start Date Time:	Sep/25/2020 10:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/16/2020 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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: [sun exposure]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Medication Error

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

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flu vaccine	Oct/14/2020	Repeating Pages
2. DELETED	2	VACCINATIONS	NO	Keytruda	Jan/UNK/2021	Repeating Pages
3.	3	VACCINATIONS	NO	Shingles virus vaccine	Jan/25/2021	Repeating Pages

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flu vaccine.]
5.	Date:	Oct/14/2020

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Deleted, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551182**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44***** THIS REPEATING FORM HAS BEEN DELETED *****[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Concomitant Medications**

1.	What is the medication identifier?	[2]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Keytruda]
5.	Date:	Jan/UNK/2021

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	[3]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Shingles virus vaccine]
5.	Date:	Jan/25/2021

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	1	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Keytruda	unk	Repeating Pages

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Incomplete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Concomitant Medications

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

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

#	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: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Radiation Treatment

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

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Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/14/2021
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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/14/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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 _____
----	----------------------------------------	-------------------------

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P7L]
5.b	Sample ID	[BS3BBY]
5.c	Sample ID	[BS3BBX]

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2P7J]
-----	-----------	----------

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/23/2021 12:12
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT **Form:** DISPOSITION - TREATMENT
- Unscheduled

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/26/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-08-2021 09:03:22 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-03-2020 16:18:16 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
6	Jan-21-2021 14:40:45 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Unknown <hr/> Unknown

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
7	Mar-08-2021 08:32:28 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Dose frequency is every 3 weeks
7	Jan-21-2021 14:40:24 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Dose frequency is weekly

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-23-2021 15:06:36 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-08-2021 09:03:22 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, 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.

Julie Glazier	N/A	Mar-08-2021 08:32:28 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-24-2021 08:06:55 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** Investigator Signature -
Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551182**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

Elle Billman	N/A	Feb-23-2021 15:48:01 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-23-2021 15:13:14 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Elle Billman	N/A	Feb-23-2021 13:25:37 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-12-2021 15:49:45 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Julie Glazier	N/A	Feb-12-2021 15:20:10 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Feb-09-2021 09:49:15 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Megan Pastores	N/A	Feb-05-2021 15:29:13 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-25-2021 09:18:31 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Ricell Ann Piojo	N/A	Jan-24-2021 22:24:59 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-22-2021 16:14:20 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Bethany Wexler	N/A	Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Jan-21-2021 18:44:34 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Julie Glazier	N/A	Jan-21-2021 14:35:14 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Nov-17-2020 18:08:49 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

Bethany Wexler	N/A	Nov-17-2020 14:19:09 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Helen Stacey	Approved	Oct-27-2020 16:57:08 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HelenStacey, 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.

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-03-2020 16:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Consent Was:

Date	Location	User	Value	Reason
Sep-03-2020 16:17:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: OBTAINED Date Written Consent O btained Sep/3/2020	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-03-2020 16:16:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10551182	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:16:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1958	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NOT HISPANIC OR LAT INO(A) OR OF SPANIS H ORIGIN	Initial Entry

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

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-03-2020 16:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: WHITE	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 16:18:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-03-2020 16:18:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: COMPLETED	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551182**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Sep-03-2020 16:22:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Seasonal allergies Start Date: UNK/UNK/1970 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 13:50:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-22-2021 10:18:51 (UTC-08:00) Pacific Time (US &	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	Changed data per query

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551182**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

Canada)				
Jan-20-2021 07:06:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - SAE reports subject has HTN (2019 onset) & metoprolol Rx (Oct 2020 start), but not recorded on prior Med Hx. Consider safety relevance of cardiovasc conditions for COVID & record, if appropriate
Sep-03-2020 16:22:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Seasonal allergies	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/1970	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:15 (UTC-08:00) Pacific	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)				
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1.b

Date	Location	User	Value	Reason
Jan-22-2021 10:17:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Hypertension Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

1.b Line/MH Number:

Date	Location	User	Value	Reason
Jan-22-2021 10:17:37 (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
Jan-22-2021 10:17:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Hypertension	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jan-22-2021 10:17:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: UNK/UNK/2019	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Jan-22-2021 10:17:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/3/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 109.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 180.4	Initial Entry

5. Unit:

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 33.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Record Identifier:: Temperature: 37.1 Temperature C Unit: Temperature Location:: FOREH EAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 1	Initial Entry

7.a Temperature:

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 37.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: FOREHEAD	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-03-2020 16:19:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/3/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 251860	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 16:30:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 16:30:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 16:31:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:30:54 (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.

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-03-2020 16:30:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry
-------------------------------------------------------------------------	-----------------	---------------------------------	--------------------------------------------------------------------	---------------

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:31:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP91XX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:31:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP91XX	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 16:31:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP91XY	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:31:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP91XY	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 16:31:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPFTF1	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:31:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPFTF1	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-03-2020 16:31:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BPFTF2	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:31:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BPF2F2	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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 16:31:43 (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-03-2020 16:31:43 (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-03-2020 16:31:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:31:43 (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.

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-03-2020 16:31:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:31:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sample ID: BP91XV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:31:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: BP91XV	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20 (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-03-2020 16:19:20 (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-03-2020 16:19:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Sep/3/2020 15:09	Initial Entry

5. Anatomical Location:

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20 (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-03-2020 16:19:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20 (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-03-2020 16:19:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFI ED OBSERVATION PERI OD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-03-2020 16:19:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-25-2020 14:48:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/25/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/25/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-25-2020 14:48:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Record Identifier:: Temperature: 36.5 Temperature C Unit: Temperature FOREH Location:: EAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
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090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-25-2020 14:48:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: 36.5	Initial Entry
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2.a Unit:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: FOREHEAD	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-25-2020 15:23:42 (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-25-2020 15:23:42 (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-25-2020 15:24:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-25-2020 15:23:42 (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.

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Sep-25-2020 15:23:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES Date of Collection: Sep/25/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Sep-25-2020 15:24:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sample ID: BPV0BF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 15:24:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: BPV0BF	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-25-2020 14:48:58 (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-25-2020 14:48:58 (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-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/25/2020 13:41	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:58 (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-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:58 (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-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFI ED OBSERVATION PERI OD	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Sep-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	<u>Data Entry:</u> YES	Initial Entry
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090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-26-2020 12:18:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Oct/26/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-26-2020 15:08:45 (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-26-2020 15:08:45 (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-26-2020 15:09:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-26-2020 15:08:45 (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.

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Oct-26-2020 15:08:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection: Oct/26/2020	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------------	---------------------------------------------------------------------	---------------

5.a

Date	Location	User	Value	Reason
Oct-26-2020 15:09:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID: BR2PGK	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 15:09:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2PGK	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-26-2020 15:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID: BS8B38	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.b Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 15:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> BS8B38	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-26-2020 15:09:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> Sample ID: BS8B37	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 15:09:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> BS8B37	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-26-2020 12:18:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Oct/26/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-26-2020 12:18:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-26-2020 12:18:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: COMPLETED	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

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: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (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
Sep-25-2020 14:55:28 (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
Nov-17-2020 14:19:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Bethany Wexler (pfe.bwexler)	Data Entry: Melanoma	New Information
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Basal Cell Cancer	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Subject Initials: ---

Generated By: pfe.levisse

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Jan-22-2021 12:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Nov/16/2020 UNK:UNK	New Information
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Sep/25/2020 10:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 02:45:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 3: Closed	Response satisfies query
Jan-13-2021 09:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Query 3: Answered	Adverse event is still ongoing.
Jan-12-2021 09:42:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 3: Opened	GPD CLINQUERY: Please confirm that adverse event is still ongoing.
Nov-20-2020 03:43:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 2: Closed	Response satisfies query

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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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551182**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

Nov-19-2020 10:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Answered	confirmed, ongoing
Nov-19-2020 08:25:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 2: Opened	GPD CLINQUERY: Please confirm that adverse event is still ongoing and without change to severity.
Nov-17-2020 04:55:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Closed	Closing query pending confirmation.
Nov-13-2020 06:55:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Opened	GPD CLINQUERY: Please confirm that adverse event, onset date 25-SEP-20 is still ongoing and without change to severity.
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Jan-22-2021 08:58:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: 2	Changed Information
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Jan-24-2021 22:24:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Jan-22-2021 09:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Jan-21-2021 14:35:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE Melanoma: Response to "Is the adverse event serious?" is 'Yes' but "Serious

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

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				Adverse Event Number" is blank.
Jan-21-2021 14:35:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Jan-21-2021 14:35:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p>	Changed Information

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Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

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			NO Other medically important serious event YES	
Jan-19-2021 08:15:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Serious criteria for event Melanoma are NONE; however, SAE report was submitted with serious criteria Medically Important. Please review, harmonize reporting and update where appropriate
Nov-20-2020 03:27:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Closed	Response satisfies query
Nov-19-2020 14:11:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Bethany Wexler (pfe.bwexler)	Query 1: Answered	This event does not meet SAE criteria at this time.
Nov-19-2020 07:53:49 (UTC-08:00)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Opened	GPD CLINQUERY: Please confirm

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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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551182**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

Pacific Time (US & Canada)				that the adverse event does not meet protocol criteria for serious adverse event including important medical event.
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	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
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i>	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

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			Sun exposure	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-22-2021 09:47:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-21-2021 14:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-21-2021 14:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Changed Information
Jan-19-2021 08:16:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Con Med is 'NO', however, SAE report states subject is receiving

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Visit: Logs - Unscheduled

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Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

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				pembrolizumab. Please review, harmonize reporting, and update where applicable.
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-22-2021 09:47:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-21-2021 14:35:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-21-2021 14:35:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Changed Information
Jan-19-2021 08:16:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical non-drug Treatment is 'NO', however, SAE report

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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:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551182**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

				states subject is receiving radiation therapy. Please review, harmonize reporting, and update where applicable
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NOT RECOVERED/NO T RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

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Jan-24-2021 22:24:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2021036886	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (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
Jan-22-2021 13:02:13 (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
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: skin lesion of scalp	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sep/25/2020 10:00	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO End Date Time: Nov/16/2020 UNK:U NK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	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
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	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.

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551182**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT RELATED If Not Related to study t reatment(s), this event is due to: OTHER <i>If Other, specify:</i> sun exposure	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

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Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: RECOVERED/RESOLVED WITH SEQUELAE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-26-2020 12:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Jan-22-2021 08:55:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Bethany Wexler (pfe.bwexler)	Form Deleted	Transcription Error
Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Bethany Wexler (pfe.bwexler)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-05-2021 15:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-26-2020 12:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-26-2020 12:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-26-2020 12:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-26-2020 12:18:53 (UTC-08:00) Pacific	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Flu vaccine.	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)				
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5. Date:

Date	Location	User	Value	Reason
Oct-26-2020 12:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Oct/14/2020	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US &	ACV0PFEINFP6000	Bethany Wexler (pfe.bwexler)	Data Entry: Keytruda	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

*** THIS REPEATING FORM HAS BEEN DELETED ***

Canada)

5. Date:

Date	Location	User	Value	Reason
Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Bethany Wexler (pfe.bwexler)	Data Entry: Jan/UNK/2021	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-05-2021 15:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-05-2021 15:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-05-2021 15:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-12-2021 17:06:47	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle	Query 1: Clo	Discrepancy has been

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1055**Site Name:** (1055) Diablo Clinical Research Incorporated**Subject No:** 10551182**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		(pfe.PFETMS)	sed	closed.
Feb-12-2021 15:20:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	New Information
Feb-12-2021 15:20:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry : Shing les vir us vac cine	New Information
Feb-05-2021 19:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Op ened	Clarify SHINGLES as follows...Are you reporting SHINGLES VIRUS VACCINE if so edit as such. Otherwise if reporting a non drug concept please move to appropriate panel for

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

				MedDRA coding. Thank you
Feb-05-2021 15:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry : Shingles	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Feb-05-2021 15:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Jan/25/2021	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: CONCOMITANT IMMU NOSUPPRESSIVE THE RAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Keytruda	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5. Dose:

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: unk	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jan-21-2021 14:40:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Unknown	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Mar-08-2021 22:23:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Mar-08-2021 08:33:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	option not available in drop down menu, see in item level comment
Mar-07-2021 21:28:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Please complete this item. Thank you.

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

8. Route:

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: Jan/UNK/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Data Entry: YES	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (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: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-05-2021 15:29:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Jan/14/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: FURTHER VACCINATION CONFIRMATION - eCRF
Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Date	Location	User	Value	Reason
Feb-05-2021 15:30:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Participant is willing to r eturn for Vaccination 3 Participant is: eligible per local/nati onal recommendation s and confirmed to ha ve received only plac ebo at Vaccination 1/ 2	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-05-2021 15:29:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: Jan/14/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-05-2021 15:29:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VA CCINATION	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 13:25:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/23/2021	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Consent Was:

Date	Location	User	Value	Reason
Feb-23-2021 15:06:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> OBTAINED Date Written Consent O btained Feb/23/2021	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-23-2021 15:06:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/23/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-23-2021 15:06:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-23-2021 15:06:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: COMPLETED	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Feb-23-2021 15:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 15:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-23-2021 15:48:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 15:48:27 (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.

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-23-2021 15:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection: Feb/23/2021	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------------	---------------------------------------------------------------------	---------------

5.a

Date	Location	User	Value	Reason
Feb-23-2021 15:48:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID: BR2P7L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:48:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2P7L	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-23-2021 15:48:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID: BS3BBY	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

5.b Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:48:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> BS3BBY	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-23-2021 15:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> Sample ID: BS3BBX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	<u>Data Entry:</u> BS3BBX	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Feb-23-2021 15:48:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 15:48:01 (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
Feb-23-2021 15:48:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 15:48:01 (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.

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-23-2021 15:48:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES Date of Collection: Feb/23/2021	Initial Entry
-------------------------------------------------------------------------	-----------------	--------------------------------	---------------------------------------------------------------------	---------------

5.a

Date	Location	User	Value	Reason
Feb-23-2021 15:48:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Sample ID: BR2P7J	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:48:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: BR2P7J	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (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
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Feb/23/2021 12:12	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (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
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
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090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:44

Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: YES	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject Status

Date	Location	User	Value	Reason
Oct-26-2020 12:18:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-03-2020 16:19:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZ ED	Initial Entry
Sep-03-2020 16:18:29 (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-26-2020 12:18:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/26/2020	Initial Entry
Oct-26-2020 12:18:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry
Sep-03-2020 16:19:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry

090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1055

Subject No: 10551182

Generated By: pfe.levisse

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1055) Diablo Clinical Research Incorporated

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Sep-03-2020 16:18:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry
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090177e196ae407c\Final\Final On: 01-Apr-2021 05:41 (GMT)

Header Text: c4591001
Visit: Investigator Signature - Unscheduled
Form Version: 22-Apr-2020 21:04
Site No: 1055
Subject No: 10551182
Generated By: pfe.levisse
Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History
Form Status: Data Complete, Signed, Verified
Site Name: (1055) Diablo Clinical Research Incorporated
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-27-2020 13:37:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Data Entry: Click Here to Enable	Initial Entry