

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

[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

<b>Header Text:</b> c4591001	<b>Form:</b> MAIN INFORMED CONSENT
<b>Visit:</b> COHORT_SELECTION	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1011) Clinical Research Consulting, LLC
<b>Site No:</b> 1011	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10111029	<b>Generated Time (GMT):</b> 29-Mar-2021 04:21
<b>Generated By:</b> pfe.levissc	

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DEMOGRAPHY

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10111029]
2.	Birth Date:	(b) (6) 1943
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:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levissc

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Aug/13/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111029

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
<del>1.b</del>	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	<del>[Other Medical Condition]</del>
	Start Date:	<del>UNK/UNK/1998</del>
	Ongoing:	<del>NO</del> <del>End Date:</del> <del>UNK/UNK/1998</del>
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Postmenopausal]
	Start Date:	UNK/UNK/1994
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Overactive Bladder]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Post Herpetic Neuralgia]
	Start Date:	Apr/10/2020
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Shingles]
	Start Date:	Apr/1/2020
	Ongoing:	NO End Date: Apr/UNK/2020
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dilation and Curettage]
	Start Date:	UNK/UNK/1998
	Ongoing:	NO End Date: UNK/UNK/1998
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Facelift]
	Start Date:	UNK/UNK/2001
	Ongoing:	NO End Date: UNK/UNK/2001

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**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Uterine Bleeding]
	Start Date:	UNK/UNK/1998
	Ongoing:	NO End Date: UNK/UNK/1998

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**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/13/2020
2.	Weight:	[166.8]
3.	Unit:	LB
4.	Height:	[64.0]
5.	Unit:	in
6.	Body Mass Index:	[28.6]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.3]
	Unit:	F
	Temperature Location:	FOREHEAD

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**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/13/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levissc

**Form:** RANDOMIZATION

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/13/2020
2.	Randomization Number:	[228332]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/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	[BN5Z5C]
5.b	Sample ID	[BN5Z5D]
5.c	Sample ID	[BN5Z5F]
5.d	Sample ID	[BL9NCC]
5.e	Sample ID	[BL9NCF]
5.f	Sample ID	[BL9NCD]
5.g	Sample ID	[BL9NCG]

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**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1011  
**Subject No:** 10111029  
**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1011) Clinical Research Consulting, LLC  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/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	[BN5Z50]
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**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** VACCINATION

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[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/13/2020 16:47
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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/31/2020
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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

[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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

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**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/31/2020
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**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/31/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[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	[BN5ZLR]
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090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** VACCINATION

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[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 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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/1/2020
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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

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**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

[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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/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	[BP9T17]
5.b	Sample ID	[BP9T18]
5.c	Sample ID	[BP9T19]
5.d	Sample ID	[BL9N04]
5.e	Sample ID	[BL9N05]

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**Illness Details**

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisc

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Oct/1/2020
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:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Disposition - Follow-Up**

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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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090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Perforated Appendicitis	Sep/12/2020 08:00	NO End Date Time:  Sep/15/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Feculant Peritonitis	Sep/14/2020 UNK:UNK	NO End Date Time:  Sep/18/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen, Not Complete

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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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:	Sep/12/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/15/2020 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 YES
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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen, Not Complete

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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: [Appendicitis]
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	[2020381781]

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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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)	[Feculant Peritonitis]
4.	Start Date Time:	Sep/14/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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: [Perforated Appendicitis]
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	[2020381781]

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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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	[ ]

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)



**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

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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:	//

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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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?	

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:	

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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?	

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Date of Visit**

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/12/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levissc

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Death Details**

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

**Cause of Death**

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levissc

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[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, Frozen, Verified

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[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:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/18/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[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	[BR6BY5]
5.b	Sample ID	[BS08BB]
5.c	Sample ID	[BS08B3]

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[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	[BR6BY6]
-----	-----------	----------

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[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 15:01
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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/8/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/8/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[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	[BR6BZN]
-----	-----------	----------

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** VACCINATION

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[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 13:30
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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/8/2021
2.	Erroneous Visit	



<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME
<b>Visit:</b> V103_MONTH1	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:04	<b>Site Name:</b> (1011) Clinical Research Consulting, LLC
<b>Site No:</b> 1011	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10111029	<b>Generated Time (GMT):</b> 29-Mar-2021 04:21
<b>Generated By:</b> pfe.lewissc	

[eCRF Audit Trail History](#)

Contact Outcome		
1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/8/2021
3.	Comments:	[ ]

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Contact Outcome**

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**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:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**Contact Outcome**

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

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Mar/8/2021
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:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Subject Status**

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

**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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
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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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Susann Varano	Approved	Mar-09-2021 07:59:27 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, SusannVarano, 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.

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-13-2020 18:43:00 (UTC-05:00) Eastern Time (US & Canada)	Linda Welch (pfe.lwelch)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER  
VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-19-2021 07:05:12 (UTC-05:00) Eastern Time (US & Canada)	Linda Welch (pfe.lwelch)	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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

[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
Susann Varano	Approved	Mar-09-2021 07:59:27 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, SusannVarano, 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.

Linda Welch	N/A	Mar-08-2021 13:50:10 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Susann Varano	Approved	Feb-25-2021 14:02:46 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, SusannVarano, 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.

Linda Welch	N/A	Feb-23-2021 12:39:55 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

Susann Varano	Approved	Feb-11-2021 10:19:46 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, SusannVarano, 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.

Linda Welch	N/A	Feb-08-2021 15:05:29 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Susann Varano	Approved	Jan-28-2021 10:21:13 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, SusannVarano, 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.

Linda Welch	N/A	Jan-26-2021 13:07:35 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Susann Varano	Approved	Jan-20-2021 13:34:16 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

**Affidavit:**

By my dated signature below, I, SusannVarano, 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.

Linda Welch	N/A	Jan-18-2021 11:04:54 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Lauren Calgreen	Approved	Oct-29-2020 17:25:00 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, LaurenCalgreen, 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.

Linda Welch	N/A	Oct-29-2020 15:46:50 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Susann Varano	Approved	Oct-27-2020 11:31:34 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, SusannVarano, 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.

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

Susann Varano	N/A	Oct-27-2020 11:31:02 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Lauren Calgreen	Approved	Oct-09-2020 13:58:03 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, LaurenCalgreen, 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.

Rachel Pierce	N/A	Oct-07-2020 07:10:26 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Susann Varano	Approved	Oct-06-2020 13:57:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, SusannVarano, 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.

Linda Welch	N/A	Oct-01-2020 14:11:40 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

Susann Varano	Approved	Sep-10-2020 14:53:22 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, SusannVarano, 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:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levissc

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[Back to Form](#)

**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Aug-13-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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***1. Consent Was:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-13-2020 18:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/13/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1011

Subject No: 10111029

Generated By: pfe.levissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-13-2020 18:41:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10111029	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-13-2020 18:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1943	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-13-2020 18:42:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-13-2020 18:42:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 18:42:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-13-2020 18:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-13-2020 23:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-13-2020 23:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-13-2020 23:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111029

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[Back to Form](#)

*1.a*

Date	Location	User	Value	Reason
Aug-13-2020 23:01:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 1 Medical History Term: Insomnia Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-13-2020 23:01:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 23:01:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Insomnia	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Aug-13-2020 23:01:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

*1.a Ongoing:*

Date	Location	User	Value	Reason
Aug-13-2020 23:01:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> YES	Initial Entry

*1.b*

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Aug-14-2020 09:11:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Line/MH Num 2</b> <b>ber:</b> <b>Medical Histor</b> Other Medical C <b>y Term:</b> ondition <b>Start Date:</b> UNK/UNK/1998 <b>Ongoing:</b> NO End Date:  UNK/UNK/1 998	Changed Information (DELETED)
Aug-13-2020 23:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num 2</b> <b>ber:</b> <b>Medical Histor</b> Other Medical C <b>y Term:</b> ondition <b>Start Date:</b> UNK/UNK/1998 <b>Ongoing:</b> NO End Date:  UNK/UNK/1 998	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-14-2020 09:11:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<u>Data Entry:</u> 2	Changed Information <b>(DELETED)</b>
Aug-13-2020 23:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 09:11:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<u>Data Entry:</u> <del>Other Medical Condition</del>	Changed Information <b>(DELETED)</b>
Aug-13-2020 23:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe.nbaker1)	<u>Data Entry:</u> Other Medical Condition	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-14-2020 09:11:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<u>Data Entry:</u> <del>UNK/UNK/1998</del>	Changed Information <b>(DELETED)</b>
Aug-13-2020 23:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe.nbaker1)	<u>Data Entry:</u> UNK/UNK/1998	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Aug-14-2020 09:11:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<u>Data Entry:</u> <del>NO</del> <del>End Date:</del>  UNK/UNK/1998	Changed Information <b>(DELETED)</b>
Aug-13-2020 23:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe.nbaker1)	<u>Data Entry:</u> NO End Date:	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

UNK/UNK/1998

*I.c*

Date	Location	User	Value	Reason
Aug-13-2020 23:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Postmenopausal <b>Start Date:</b> UNK/UNK/1994 <b>Ongoing:</b> YES	Initial Entry

*I.c Line/MH Number:*

Date	Location	User	Value	Reason
Aug-13-2020 23:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 23:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Postmenopausal	Initial Entry

*I.c Start Date:*

Date	Location	User	Value	Reason
Aug-13-2020 23:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> UNK/UNK/1994	Initial Entry

*I.c Ongoing:*

Date	Location	User	Value	Reason
Aug-13-2020 23:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> YES	Initial Entry

*I.d*

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Aug-13-2020 23:03:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 4 <b>Medical History Term:</b> Overactive Bladder <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> YES	Initial Entry

**1.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 23:03:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 23:03:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Overactive Bladder	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 23:03:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 23:03:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> YES	Initial Entry

**1.e**

Date	Location	User	Value	Reason
Aug-14-2020 07:48:06	ACV0PFEINFP6000	Rachel	<b>Data Entry:</b>	Transcription Error

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

(UTC-05:00) Eastern Time (US & Canada)		Pierce (pfe.spierce)	<b>Line/MH Number:</b> 5 <b>Medical History Term:</b> Post Herpetic Neuralgia <b>Start Date:</b> Apr/10/2020 <b>Ongoing:</b> YES	
Aug-13-2020 23:04:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> Post Herpetic Neuralgia <b>Start Date:</b> Apr/10/2020 <b>Ongoing:</b> YES	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

***I.e Line/MH Number:***

Date	Location	User	Value	Reason
Aug-13-2020 23:04:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 08:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-14-2020 07:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-14-2020 07:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	<b>Data Entry:</b> Post Herpetic Neuralgia	Transcription Error
Aug-14-2020 00:37:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify the term POST HERPATIC NEURALGIA as follows. Should spelling be POST HERPATIC NEURALGIA? If so, edit as such. Otherwise, clarify. Thank you.
Aug-13-2020 23:04:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe.nbaker1)	<b>Data Entry:</b> Post Herpetic Neuralgia	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

*I.e Start Date:*

Date	Location	User	Value	Reason
Aug-13-2020 23:04:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Apr/10/2020	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Aug-13-2020 23:04:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> YES	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Aug-13-2020 23:04:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 6 <b>Medical History T Shingles</b> <b>erm:</b> <b>Start Date:</b> Apr/1/2020 <b>Ongoing:</b> NO End Date: Apr/UNK/2020	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

***1.f Line/MH Number:***

Date	Location	User	Value	Reason
Aug-13-2020 23:04:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 23:04:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Shingles	Initial Entry

***1.f Start Date:***

Date	Location	User	Value	Reason
Aug-13-2020 23:04:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Apr/1/2020	Initial Entry

***1.f Ongoing:***

Date	Location	User	Value	Reason
Aug-13-2020 23:04:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO End Date: Apr/UNK/2020	Initial Entry

***1.g***

Date	Location	User	Value	Reason
Aug-13-2020 23:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> Dilation and Cur ettage <b>Start Date:</b> UNK/UNK/1998	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

			Ongoing:	NO	
				End Date:	
				UNK/UNK/1998	

**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 23:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 23:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Dilation and Curettage	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 23:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> UNK/UNK/1998	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 23:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1998	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Aug-13-2020 23:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 8	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

			<b>Medical History Term:</b> Facelift <b>Start Date:</b> UNK/UNK/2001 <b>Ongoing:</b> NO End Date: UNK/UNK/2001	
--	--	--	---	--

***1.h Line/MH Number:***

Date	Location	User	Value	Reason
Aug-13-2020 23:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 23:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Facelift	Initial Entry

***1.h Start Date:***

Date	Location	User	Value	Reason
Aug-13-2020 23:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> UNK/UNK/2001	Initial Entry

***1.h Ongoing:***

Date	Location	User	Value	Reason
Aug-13-2020 23:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO End Date: UNK/UNK/2001	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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<i>1.i</i>				
Date	Location	User	Value	Reason
Aug-14-2020 09:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> Uterine Bleeding <b>Start Date:</b> UNK/UNK/1998 <b>Ongoing:</b> NO End Date: UNK/UNK/1998	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

***1.i Line/MH Number:***

Date	Location	User	Value	Reason
Aug-14-2020 09:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 09:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Uterine Bleeding	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Aug-14-2020 09:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> UNK/UNK/1998	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Aug-14-2020 09:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO End Date: UNK/UNK/1998	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1011

Subject No: 10111029

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Date:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 166.8	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 64.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28.6	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

7.a

Date	Location	User	Value	Reason
Aug-13-2020 23:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.3 <b>Temperature Unit:</b> F <b>Temperature Locati</b> <b>on::</b> FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-13-2020 23:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-13-2020 23:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 97.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-13-2020 23:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-13-2020 23:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE
--------------------	--	--	--

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Aug-13-2020 23:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levissc

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-13-2020 23:09:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-13-2020 23:09:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 228332	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-13-2020 23:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-13-2020 23:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-14-2020 07:56:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-14-2020 03:04:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-13-2020 23:09:27 (UTC-05:00) Eastern 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-13-2020 23:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe.nbaker1)	<b>Data Entry:</b> YES Date of Collection:  Aug/13/2020	Initial Entry

**5.a**

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Aug-14-2020 07:56:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> <b>Sample ID: BN5Z5C</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 07:56:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> BN5Z5C	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Aug-14-2020 07:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> <b>Sample ID: BN5Z5D</b>	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 07:56:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> BN5Z5D	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-14-2020 07:56:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> <b>Sample ID: BN5Z5F</b>	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 07:56:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> BN5Z5F	Initial Entry

**5.d**

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Aug-14-2020 07:56:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> <b>Sample ID: BL9NCC</b>	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 07:56:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> BL9NCC	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-14-2020 07:57:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> <b>Sample ID: BL9NCF</b>	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 07:57:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> BL9NCF	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-14-2020 07:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> <b>Sample ID: BL9NCD</b>	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 07:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> BL9NCD	Initial Entry

5.g

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Aug-14-2020 07:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> <b>Sample ID: BL9NCG</b>	Initial Entry

**5.g Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 07:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> BL9NCG	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-13-2020 23:09:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-13-2020 23:09:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-14-2020 08:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-14-2020 03:45:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-13-2020 23:09:37 (UTC-05:00) Eastern 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-13-2020 23:09:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe.nbaker1)	<b>Data Entry:</b> YES Date of Collection:  Aug/13/2020	Initial Entry

**5.a**

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Aug-14-2020 08:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> <b>Sample ID:</b> BN5Z50	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 08:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	<b>Data Entry:</b> BN5Z50	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 10111029

Generated By: pfe.lewiss

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-13-2020 23:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-13-2020 23:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-13-2020 23:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-13-2020 23:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Aug/13/2020 16:47	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-13-2020 23:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-13-2020 23:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> LEFT	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**7. Route:**

Date	Location	User	Value	Reason
Aug-13-2020 23:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-13-2020 23:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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-13-2020 23:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-13-2020 23:10:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**I. Date of Visit**

Date	Location	User	Value	Reason
Sep-02-2020 12:18:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Closed	Response satisfies query
Sep-02-2020 07:56:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Query 1: Answered	Original value is correct
Sep-02-2020 03:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Opened	PDQ: Date of visit at this visit is out of window (-1 day) from Date of visit (13/Aug/2020) at VID1VX1L visit. Please reconcile and update accordingly, else confirm date is correct as is.
Aug-31-2020 23:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe.nbaker1)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:21

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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
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 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-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> <b>Symptom::</b> FA TI	Initial Entry

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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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

			GU E NO	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.b Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	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-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

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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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

2.c Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 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-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS  <b>Were fever or systemic sym</b> <b>ptoms present on the last d</b> <b>ay the Subject Diary was c</b> <b>ompleted?:</b> NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 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-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?:</b>	Initial Entry
			VO MIT ING NO	

2.e Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 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-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?:</b>	Initial Entry
			DIA RR HE A NO	

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011**Site Name:** (1011) Clinical Research Consulting, LLC**Subject No:** 10111029**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**2.f Symptom:**

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 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-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MUS CLE PAI N  <b>Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:</b>	Initial Entry

**2.g Symptom:**

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NEW OR WORSE NED MUSCL E 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-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

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2.h

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:</b>	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NEW OR WORSE NED JOI NT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> LEFT	Initial Entry

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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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

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5.a

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 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-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

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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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 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-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 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-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 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-31-2020 23:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1011

Subject No: 10111029

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Date:**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.6 <b>Temperature Unit:</b> F <b>Temperature Locati on::</b> FOREHE AD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> 97.6	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Aug-31-2020 23:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:52 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Aug-31-2020 23:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-31-2020 23:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-31-2020 23:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-01-2020 08:00:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-01-2020 02:28:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 23:41:03 (UTC-05:00) Eastern 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 23:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe.nbaker1)	<b>Data Entry:</b> YES Date of Collection:  Aug/31/2020	Initial Entry

**5.a**

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Sep-01-2020 08:00:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Sample ID:</b> BN5ZLR	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-01-2020 08:00:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> BN5ZLR	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 10111029

Generated By: pfe.lewiss

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-31-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-31-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-31-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-31-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> Aug/31/2020 14:13	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-31-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-31-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**7. Route:**

Date	Location	User	Value	Reason
Aug-31-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-31-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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-31-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-01-2020 14:11:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Oct/1/2020	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:21

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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
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic sym</b> N <b>ptoms present on the last da</b> O <b>y the Subject Diary was co</b> <b>mpleted?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Symptom::</b> FA TIG	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011**Site Name:** (1011) Clinical Research Consulting, LLC**Subject No:** 10111029**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**2.c Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS <b>Were fever or systemic sym</b> NO <b>ptoms present on the last da</b> <b>y the Subject Diary was co</b> <b>mpleted?:</b>	Initial Entry

**2.d Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> 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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry
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*2.e Symptom:*

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

*2.f*

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011**Site Name:** (1011) Clinical Research Consulting, LLC**Subject No:** 10111029**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**2.f Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MUS CLE PAI N  <b>Were fever or system NO ic symptoms present on the last day the Su bject Diary was comp leted?:</b>	Initial Entry

**2.g Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> 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
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

2.h

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</b> NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NEW OR WORSE NED JOI NT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

5.a

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reaction NO s present on the last day th e Subject Diary was compl eted?:</b>	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG  <b>Were injection site reactio NO ns present on the last day t he Subject Diary was com pleted?:</b>	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 14:12:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-01-2020 15:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-01-2020 15:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-01-2020 15:49:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 15:49:13 (UTC-05:00) Eastern 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-01-2020 15:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> YES Date of Collection:  Oct/1/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-01-2020 15:49:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Sample ID:</b> BP9T17	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

5.a Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 15:49:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> BP9T17	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-01-2020 15:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Sample ID: BP9T18</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 15:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> BP9T18	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-01-2020 15:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Sample ID: BP9T19</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 15:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> BP9T19	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-02-2020 07:31:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Sample ID: BL9N04</b>	Transcription Error

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Oct-01-2020 15:50:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Sample ID:</b> BL9N05	Initial Entry
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5.d Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 15:21:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clos ed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-02-2020 07:31:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Oct-02-2020 07:31:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data E ntry:</b> BL9N0 4	Transcription Error
Oct-01-2020 21:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW4871677;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-01-2020 15:50:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data E ntry:</b> BL9N0 5	Initial Entry

5.e

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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

Oct-01-2020 15:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> <b>Sample ID:</b> BL9N05	Initial Entry
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**5.e Sample ID**

Date	Location	User	Value	Reason
Oct-02-2020 15:21:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clos ed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-02-2020 07:32:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Query 1: Ans wered	Original value is correct
Oct-01-2020 21:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW4871678;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-01-2020 15:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data E ntry:</b> BL9N0 5	Initial Entry

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**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-02-2020 07:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Oct/1/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-02-2020 07:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-02-2020 07:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> COMPLETED	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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Date	Location	User	Value	Reason
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Form Created	



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Form Created	

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Not Complete

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Category:**

Date	Location	User	Value	Reason
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-09-2020 08:02:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ankita Thakur (pfe.thakua20)	Query 5: Clos ed	Response satisfies query.
Oct-08-2020 14:57:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Ans wered	Changed Information
Oct-08-2020 14:57:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data E ntry:</b> Perfora ted Ap pendici tis	Changed Information
Oct-08-2020 13:24:46 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 5: Ope ned	DM: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Not Complete

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

Canada)				entry and re-entering the data (without using copy and paste).
Oct-08-2020 02:30:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Closed	Response satisfies query
Oct-08-2020 02:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	Response satisfies query
Oct-08-2020 00:14:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-07-2020 14:43:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Query 1: Answered	Left quadrant pain due to Appendicitis
Oct-07-2020 11:30:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reopened	CLINICAL SAE report states location of abd pain was 'left right quadrant pain; is this Lt & Rt pain location, or another location was being described. Please leave open until SAE safety submission submitted with clarification
Oct-07-2020 07:36:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 4: Closed	Discrepancy has been closed.

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1011**Subject No:** 10111029**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Not Complete**Site Name:** (1011) Clinical Research Consulting, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

Oct-07-2020 07:10:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Ans wered	changed information based on instructions
Oct-07-2020 07:10:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Ans wered	changed information based on instructions
Oct-07-2020 07:10:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	changed information based on instructions
Oct-07-2020 07:10:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	<b>Data E ntry:</b> Perfor ated Ap pendici tis	changed information based on instructions
Oct-06-2020 22:41:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 3: Reis sued:O pened	SAE RECON 1: Please consider to split the term and enter Feculent peritonitis as separate entry.
Oct-06-2020 22:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 2: Reis sued:O pened	SAE RECON 1: Please consider to split the term into separate entries to facilitate reconciliation of events in SDB data.
Oct-06-2020 13:17:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 4: Ope ned	Multiple concepts in the term PERFORATED APPENDICITIS WITH FECULENT PERITONITIS. Split the term into PERFORATED APPENDICITIS and

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Not Complete

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

				FECULENT PERITONITIS and report as separate entries. Thank you.
Oct-06-2020 10:02:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Oct-06-2020 10:02:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Oct-06-2020 10:02:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-06-2020 10:02:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	<b>Data Entry:</b> Perforated Appendicitis with feculent peritonitis	New Information
Oct-05-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Pijojo (pfe.quiror)	Query 3: Opened	SAE RECON:AER#2020381781, the SAE term in SDB was updated to 'Perforated appendicitis with feculent peritonitis'.However, 'feculent peritonitis' was missing in AE CRF. Please confirm and update CRF.If safety update is required, submit a follow-up SAE Form

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Not Complete

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

Oct-05-2020 09:04:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 2: Opened	SAE RECON:AER#2020381781, the term in SDB was updated to 'Perforated appendicitis with feculent peritonitis'. Please confirm if term in AE CRF should be updated to PERFORATED APPENDICITIS. If safety update is required, please submit a follow-up form.
Oct-02-2020 10:19:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL SAE report states location of abd pain was 'left right quadrant pain'; please clarify in a SAE safety update if this was Lt & Rt pain location, or another location was being described
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Appendicitis	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-07-2020 11:27:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-07-2020 07:10:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-07-2020 07:10:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	<b>Data Entry:</b> Sep/12/2020 08:00	New Information
Oct-07-2020 05:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 1: Opened	SAE RECON:AER#2020381781 onset date was updated to

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Not Complete

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

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				12Sep2020 in Safety database however, recorded as 14Sep2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Sep/14/2020 08:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-01-2020 17:10:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-01-2020 17:10:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO End Date Time:  Sep/15/2020 UNK:UNK	Transcription Error
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Appendicitis End Date 15/Oct /2020, is a future date relative to when it was entered on 01/Oct/2020. Please correct.
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO End Date Time:  Oct/15/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-01-2020 17:09:28 (UTC-05:00) Eastern	ACV0PFEINFP6000	Linda Welch	<b>Data Entry:</b> 3	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Not Complete

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

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Time (US & Canada)

(pfe.lwelch)

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 23:32:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Oct-27-2020 09:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Query 3: Answered	SAE follow up report send 27OCT2020. Subject verbaly reported COVID test done during admittance
Oct-25-2020 21:27:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020381781] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-02-2020 07:53:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 17:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-01-2020 17:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or bir th defect?	Transcription Error

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			<p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Appendicitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-01-2020 17:09:28 (UTC-05:00) Eastern	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> YES	Initial Entry

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Time (US & Canada)			<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>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</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
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>	Initial Entry

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			Appendicitis	
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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> YES	Initial Entry

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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-09-2020 17:05:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-08-2020 15:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-08-2020 15:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	<b>Data Entry:</b> YES	Transcription Error
Oct-08-2020 15:44:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - SAE reports states subject had an appendectomy on 14 Sep 2020; please record this non-drug treatment
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 17:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
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**Generated By:** pfe.levisse

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Oct-02-2020 07:53:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020381781	Initial Entry
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Subject No: 10111029

Generated By: pfe.lewissc

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**1. Category:**

Date	Location	User	Value	Reason
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-09-2020 06:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Oct-08-2020 09:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Query 1: Answered	Follow up report submitted with correct dat of birth
Oct-08-2020 05:55:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020389577 ,the date of birth was missing in Safety database but was recorded as (b) (6) 1943 in AE CRF. Please confirm if date of birth was reported. If safety update is required, please submit a follow-up form.
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Feculant Peritonitis	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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Oct-08-2020 05:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 1: Closed	SDB onset date 14Sep2020: No Discrepancy
Oct-08-2020 02:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 1: Opened	SAE RECON: AER#2020381781 onset date was updated to 12Sep2020 in Safety database however, recorded as 14Sep2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Sep/14/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO End Date Time:  Sep/18/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> 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).

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Date	Location	User	Value	Reason
Oct-30-2020 01:27:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jayesh Yeole (pfe.yeolej)	Query 3: Closed	Data updated.
Oct-29-2020 15:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Oct-29-2020 15:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<p><b>Data Entry:</b></p> <p>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>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Transcription Error
Oct-29-2020 14:24:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 3: Opened	The seriousness criteria "Is this serious event life threatening?" is not

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				answered, please complete this question. Thank you.
Oct-08-2020 10:20:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 2: Closed	Response satisfies query
Oct-08-2020 07:44:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Query 2: Answered	they all have been completed
Oct-08-2020 03:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 2: Reissued:Opened	DM: Please verify and update responses for all seriousness criteria (Life-threatening; Important medical event). Thank you.
Oct-08-2020 02:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 14:43:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Query 2: Answered	hospitalization is marked as yes
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Feculant Peritonitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?	Initial Entry

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			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	
			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.**

Date	Location	User	Value	Reason
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Oct-09-2020 06:05:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Oct-08-2020 09:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Query 1: Answered	Follow up report submitted with Causality questions answered
Oct-08-2020 05:57:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020389577, causality was recorded as

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

				NO DATA in Safety database but was recorded as NOT RELATED in AE CRF. Please confirm correct causality. If safety update is required, please submit a follow-up form.
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Perforated Appendicitis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 13:00:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	Linda Welch	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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**Header Text:** c4591001

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**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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Time (US & Canada)

(pfe.lwelch)

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

Date	Location	User	Value	Reason
Oct-07-2020 13:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Oct-09-2020 06:03:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020381781	SDB AER number updated
Oct-08-2020 05:52:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020389577	updated AER numnber
Oct-08-2020 02:35:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020381781	Initial Entry

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**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-26-2021 14:12:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kelsey Smith (pfe.smitk160)	Query 1: Closed	Response satisfies query
Jan-26-2021 13:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-26-2021 13:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Jan/12/2021	New Information
Jan-25-2021 12:55:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Louis Scalia (pfe.scalil01)	Query 1: Opened	Per source subject was contacted on 12Jan21, but EDC noted 11Jan21. Please confirm if this is correct and adjust data accordingly.
Jan-18-2021 11:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** Potential ReVax Initial Contact -  
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1011**Subject No:** 10111029**Generated By:** pfe.levissc**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1011) Clinical Research Consulting, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Jan-18-2021 11:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 11:05:07 (UTC-05:00) Eastern 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-18-2021 11:05:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national reco mmendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-23-2021 17:29:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_36
Feb-23-2021 12:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-23-2021 12:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry</b> : Jan/12 /2021	Transcription Error
Feb-22-2021 23:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7351085;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Jan-18-2021 11:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry</b> : Jan/11 /2021	Initial Entry

**2. Primary Reason for Unblinding:**

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Jan-18-2021 11:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-19-2021 07:04:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Consent Was:**

Date	Location	User	Value	Reason
Jan-19-2021 07:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/18/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-19-2021 07:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-19-2021 07:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-19-2021 07:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-19-2021 07:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-19-2021 07:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-19-2021 07:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-19-2021 07:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-19-2021 07:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Jan-19-2021 07:05:55 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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, Frozen, Verified

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-19-2021 07:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Jan-19-2021 07:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Jan-19-2021 07:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1011**Site Name:** (1011) Clinical Research Consulting, LLC**Subject No:** 10111029**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-19-2021 08:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-19-2021 08:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-19-2021 08:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 08:55:15 (UTC-05:00) Eastern 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-19-2021 08:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspan)	<b>Data Entry:</b> YES Date of Collection:  Jan/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-19-2021 08:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspan)	<b>Data Entry:</b> <b>Sample ID:</b> BR6BY5	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

5.a Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 08:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	<b>Data Entry:</b> BR6BY5	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-19-2021 08:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	<b>Data Entry:</b> <b>Sample ID: BS08BB</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 08:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	<b>Data Entry:</b> BS08BB	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-19-2021 08:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	<b>Data Entry:</b> <b>Sample ID: BS08B3</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 08:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	<b>Data Entry:</b> BS08B3	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1011**Site Name:** (1011) Clinical Research Consulting, LLC**Subject No:** 10111029**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-19-2021 08:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-19-2021 08:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-19-2021 08:59:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 08:59:01 (UTC-05:00) Eastern 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-19-2021 08:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	<b>Data Entry:</b> YES Date of Collection:  Jan/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-19-2021 09:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe hspain)	<b>Data Entry:</b> <b>Sample ID:</b> BR6BY6	Transcription Error



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

Jan-19-2021 09:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe hspain)	<b>Data Entry:</b> <b>Sample ID:</b> BR6BY5	Transcription Error
Jan-19-2021 08:59:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe hspain)	<b>Data Entry:</b> <b>Sample ID:</b> BR6BY6	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-19-2021 09:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe hspain)	<b>Data Entry:</b> BR6BY6	Transcription Error
Jan-19-2021 09:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe hspain)	<b>Data Entry:</b> BR6BY5	Transcription Error
Jan-19-2021 08:59:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe hspain)	<b>Data Entry:</b> BR6BY6	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1011

Subject No: 10111029

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-19-2021 07:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-19-2021 07:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-19-2021 07:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-19-2021 07:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Jan/18/2021 15:01	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-19-2021 07:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-19-2021 07:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

**7. Route:**

Date	Location	User	Value	Reason
Jan-19-2021 07:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-19-2021 07:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-19-2021 07:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-19-2021 07:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 07:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-08-2021 15:05:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Feb/8/2021	Initial Entry

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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-08-2021 15:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-08-2021 15:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-08-2021 15:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Feb/8/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Feb-08-2021 15:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Feb-08-2021 15:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Feb-08-2021 15:05:47 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:21

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE
--------------------	--	--	--

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-08-2021 15:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Feb-08-2021 15:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Feb-08-2021 15:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111029

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-09-2021 10:17:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-09-2021 10:17:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-09-2021 10:17:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-09-2021 10:17:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 10:17:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	<b>Data Entry:</b> YES Date of Collection:  Feb/8/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-09-2021 10:17:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	<b>Data Entry:</b> <b>Sample ID:</b> BR6BZN	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levisse

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

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-09-2021 10:17:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	<b>Data Entry:</b> BR6BZN	Initial Entry



Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1011

Subject No: 10111029

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-08-2021 15:06:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-08-2021 15:06:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-08-2021 15:06:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-08-2021 15:06:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Feb/8/2021 13:30	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-08-2021 15:06:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-08-2021 15:06:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1011

Subject No: 10111029

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

7. Route:

Date	Location	User	Value	Reason
Feb-08-2021 15:06:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-08-2021 15:06:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-08-2021 15:06:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-08-2021 15:06:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 15:06:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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*I. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Mar-08-2021 13:50:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Mar/8/2021	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.levissc

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Contact Type:**

Date	Location	User	Value	Reason
Mar-08-2021 13:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Mar-08-2021 13:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> YES Date of Contact:  Mar/8/2021	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (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, Frozen, Verified

**Site No:** 1011

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject No:** 10111029

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-08-2021 13:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> Mar/8/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-08-2021 13:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-08-2021 13:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-02-2020 07:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-13-2020 23:09:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-13-2020 23:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-02-2020 07:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/1/2020	Initial Entry
Aug-13-2020 23:09:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/13/2020	Initial Entry
Aug-13-2020 23:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1011

**Subject No:** 10111029

**Generated By:** pfe.lewissc

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

**Site Name:** (1011) Clinical Research Consulting, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:21

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-27-2020 11:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Susann Varano (pfe.svarano)	<b>Data Entry:</b> Click Here to Enable	Initial Entry
Oct-27-2020 11:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Susann Varano (pfe.svarano)	<b>Data Entry:</b>	Transcription Error
Sep-10-2020 14:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae30a4\Final\Final On: 01-Apr-2021 04:11 (GMT)