

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

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	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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	[10111181]
2.	Birth Date:	(b) (6) 1963
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:	

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

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/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1011

Subject No: 10111181

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 _____
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090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1011

Subject No: 10111181

Generated By: pfe.lewissc

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	Oct/8/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111181

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

Form Comments

Medical History Details

1.	Line/MH Number:	Not Applicable _____ []
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____ []
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: HIV STATUS

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](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	---	---

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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:	Oct/8/2020
2.	Weight:	[188.0]
3.	Unit:	LB
4.	Height:	[64.0]
5.	Unit:	in
6.	Body Mass Index:	[32.3]

Vital Signs Details

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

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1011

Subject No: 10111181

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:	Oct/8/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae30a3\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: 10111181

Generated By: pfe.lewissc

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 :	Oct/8/2020
2.	Randomization Number:	[267968]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111181

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/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2VCZ]
5.b	Sample ID	[BR2VD0]
5.c	Sample ID	[BR2VCY]
5.d	Sample ID	[BL9N3Y]
5.e	Sample ID	[BL9N3Z]

090177e196ae30a3\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: 10111181

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: Oct/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9SYM]
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090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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:	Oct/8/2020 14:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	--	---

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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:	Oct/29/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[96.5]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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:	Oct/29/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111181

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: Oct/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2VM0]
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090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

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

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

Vaccination

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

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

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	Dec/1/2020
2.	Erroneous Visit	

090177e196ae30a3\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: 1011181

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: Dec/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	[BRGCLW]
5.b	Sample ID	[BRGCLY]
5.c	Sample ID	[BRGCLX]
5.d	Sample ID	[BGVV28]
5.e	Sample ID	[BGVV29]

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

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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090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111181

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

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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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

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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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: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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:	
----	-------------------------	--

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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

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: 10111181

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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090177e196ae30a3\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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

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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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: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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?	
----	--	--

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52 **Form Status:** Not Started

Site No: 1011 **Site Name:** (1011) Clinical Research Consulting, LLC

Subject No: 10111181 **Subject Initials:** ---

Generated By: pfe.levissc **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:	

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: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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:	
----	-------------------------	--

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

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_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: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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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090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

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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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: 10111181

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: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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

Unplanned Assessments

1.	Assessments	
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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: 10111181

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	Tingling around the mouth	Oct/8/2020 15:15	NO End Date Time: Oct/8/2020 16:14	Repeating Pages
2.	ADVERSE EVENT	2	Tingling at finger tips	Oct/8/2020 15:15	NO End Date Time: Oct/8/2020 16:15	Repeating Pages
3.	ADVERSE EVENT	3	Toothache	Oct/30/2020 09:00	NO End Date Time: Nov/17/2020 09:00	Repeating Pages

090177e196ae30a3\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: 10111181

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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)	[Tingling around the mouth]
4.	Start Date Time:	Oct/8/2020 15:15
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/8/2020 16:14
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	NO

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

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

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

090177e196ae30a3\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: 10111181

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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)	[Tingling at finger tips]
4.	Start Date Time:	Oct/8/2020 15:15
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/8/2020 16:15
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae30a3\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: 10111181

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

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

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

090177e196ae30a3\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: 10111181

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Toothache]
4.	Start Date Time:	Oct/30/2020 09:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/17/2020 09:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [tooth ache]

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

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

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

090177e196ae30a3\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: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1011

Subject No: 10111181

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	[]

090177e196ae30a3\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: 10111181

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

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:	//

090177e196ae30a3\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: 10111181

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	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

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?	

090177e196ae30a3\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: 10111181

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1011

Subject No: 10111181

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?	

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

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: 10111181

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/8/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

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: 10111181

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: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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:	

090177e196ae30a3\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: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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?	

090177e196ae30a3\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: 10111181

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: 10111181

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: V201_SURVEIL_CONSENT -
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: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

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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090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

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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Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1011

Subject No: 10111181

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:	[]

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: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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 and NOT confirmed to have received only placebo at Vaccination 1/2
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090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

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 :	Feb/2/2021
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: 10111181

Generated By: pfe.lewissc

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 :	//
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090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

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:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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	DISCONTINUED
2.	Subject Status Date	Oct/8/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

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
Lauren Calgreen	Approved	Feb-05-2021 09:39:15 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

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.

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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

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Item	Date	User	Comment
Form	Oct-08-2020 16:12:43 (UTC-05:00) Eastern Time (US & Canada)	Linda Welch (pfe.lwelch)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

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Item	Date	User	Comment
Form	Oct-08-2020 23:40:36 (UTC-05:00) Eastern Time (US & Canada)	Nancy Baker (pfe.nbaker1)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: VACCINATION - 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	Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	Rachel Pierce (pfe.spierce)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: VACCINATION - 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

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Item	Date	User	Comment
1	Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	Rachel Pierce (pfe.spierce)	Not Done

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

Form: VACCINATION - 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

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Item	Date	User	Comment
2	Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	Rachel Pierce (pfe.spierce)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: VACCINATION - 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

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Item	Date	User	Comment
3	Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	Rachel Pierce (pfe.spierce)	Not Done

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

Form: VACCINATION - 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

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Item	Date	User	Comment
4	Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	Rachel Pierce (pfe.spierce)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: VACCINATION - 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

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Item	Date	User	Comment
5	Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	Rachel Pierce (pfe.spierce)	Not Done

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

Form: VACCINATION - 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

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Item	Date	User	Comment
6	Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	Rachel Pierce (pfe.spierce)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: VACCINATION - 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

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Item	Date	User	Comment
7	Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	Rachel Pierce (pfe.spierce)	Not Done

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

Form: VACCINATION - 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

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Item	Date	User	Comment
8	Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	Rachel Pierce (pfe.spierce)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: VACCINATION - 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

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Item	Date	User	Comment
9	Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	Rachel Pierce (pfe.spierce)	Not Done

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

Form: VACCINATION - 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

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Item	Date	User	Comment
10	Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	Rachel Pierce (pfe.spierce)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: VACCINATION - 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

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Item	Date	User	Comment
11	Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	Rachel Pierce (pfe.spierce)	Not Done

090177e196ae30a3\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: 10111181

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
Lauren Calgreen	Approved	Feb-05-2021 09:39:15 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

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	Feb-04-2021 16:46:47 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Susann Varano	Approved	Dec-03-2020 14:53:07 (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	Dec-01-2020 13:05:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae30a3\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: 10111181

Subject Initials: ---

Generated By: pfe.levisse

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

Susann Varano	Approved	Nov-12-2020 14:26:05 (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.

Rachel Pierce	N/A	Nov-11-2020 15:49:17 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Susann Varano	Approved	Nov-10-2020 12:05:08 (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.

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1011

Subject No: 10111181

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-08-2020 16:11:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 16:11:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

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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I. Consent Was:

Date	Location	User	Value	Reason
Oct-08-2020 16:12:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: OBTAINED Date Written Consent Obtained Oct/8/2020	Initial Entry

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1011

Subject No: 1011181

Generated By: pfe.lewissc

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
Oct-08-2020 16:11:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1011181	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-08-2020 16:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1963	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-08-2020 16:12:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-08-2020 16:12:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 16:12:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: WHITE	Initial Entry

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

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-08-2020 16:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Oct/8/2020	Initial Entry

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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
Oct-08-2020 16:13:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Oct/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-08-2020 16:13:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-08-2020 16:13:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: COMPLETED	Initial Entry

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: HIV STATUS - 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 - What is the subject HIV status?

Date	Location	User	Value	Reason
Oct-08-2020 23:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1011

Subject No: 1011181

Generated By: pfe.levissc

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
Oct-08-2020 23:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: Oct/8/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: 188.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: 64.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:19 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 32.3	Initial Entry

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1011

Subject No: 1011181

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

Time (US & Canada)				
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7.a

Date	Location	User	Value	Reason
Oct-08-2020 23:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: Record Identifier:: 1 Temperature: 97.6 Temperature Unit: F Temperature Locat FOREHE ion:: AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: 97.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: FOREHEAD	Initial Entry

090177e196ae30a3\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: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

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
Oct-08-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: Oct/8/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-08-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae30a3\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: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 1011181

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-08-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: NEGATIVE	Initial Entry

090177e196ae30a3\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: 10111181

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
Oct-08-2020 23:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: Oct/8/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-08-2020 23:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: 267968	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

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
Oct-08-2020 23:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-08-2020 23:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 08:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-09-2020 03:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 23:41:46 (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-08-2020 23:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: YES Date of Collection: Oct/8/2020	Initial Entry

090177e196ae30a3\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: 1011181

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Oct-09-2020 08:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Sample ID: BR2VCZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 08:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: BR2VCZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 08:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Sample ID: BR2VD0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 08:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: BR2VD0	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-09-2020 08:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Sample ID: BR2VCY	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 08:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: BR2VCY	Initial Entry

090177e196ae30a3\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:** 1011181**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**5.d**

Date	Location	User	Value	Reason
Oct-09-2020 08:47:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Sample ID: BL9N3Y	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_06
Oct-12-2020 10:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	Query 1: An swere d	Original value is correct
Oct-12-2020 07:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW4940192;The Barcode BL9N3Y is recorded for two subjects 1011180 and 1011181. Please review and update as appropriate.
Oct-09-2020 08:47:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry : BL9N 3Y	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-09-2020 08:47:53 (UTC-05:00) Eastern	ACV0PFEINFP6000	Linda Welch	Data Entry: Sample ID: BL9N3Z	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)

(pfe.lwelch)

5.e Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_06
Oct-12-2020 10:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	Query 1: Answered	Original value is correct
Oct-12-2020 07:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4940193;The Barcode BL9N3Z is recorded for two subjects 10111180 and 10111181. Please review and update as appropriate.
Oct-09-2020 08:47:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry : BL9N 3Z	Initial Entry

090177e196ae30a3\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: 1011181

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
Oct-08-2020 23:41:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-08-2020 23:41:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 12:58:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-09-2020 03:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 23:41:59 (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-08-2020 23:41:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: YES Date of Collection: Oct/8/2020	Initial Entry

090177e196ae30a3\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: 10111181

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Oct-09-2020 12:58:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	Data Entry: Sample ID: BP9SYM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 12:58:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	Data Entry: BP9SYM	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 1011181

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-08-2020 23:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-08-2020 23:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-08-2020 23:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-08-2020 23:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: Oct/8/2020 14:40	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-08-2020 23:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-08-2020 23:42:10 (UTC-05:00) Eastern	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: LEFT	Initial Entry

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 1011181

Generated By: pfe.levissc

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

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Oct-08-2020 23:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-08-2020 23:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 23:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: YES	Initial Entry

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

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
Oct-08-2020 23:42:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Baker (pfe nbaker1)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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-29-2020 13:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Oct/29/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1011

Subject No: 10111181

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
Oct-29-2020 14:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Oct/29/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-29-2020 14:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Record Identifier:: 1 Temperature: 96.5 Temperature Unit: F Temperature Locati FOREHE on:: AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-29-2020 14:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-29-2020 15:54:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 1: Closed	Response satisfies query
Oct-29-2020 15:38:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Query 1: Answered	Original value is correct
Oct-29-2020 14:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.5 F is outside of Normal Range 97 - 99.5 F.

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1011

Subject No: 1011181

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

Oct-29-2020 14:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: 96.5	Initial Entry
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2.a Unit:

Date	Location	User	Value	Reason
Oct-29-2020 14:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-29-2020 14:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: FOREHEAD	Initial Entry

090177e196ae30a3\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: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-29-2020 13:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-29-2020 13:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-29-2020 13:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Oct/29/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-29-2020 13:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-29-2020 13:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae30a3\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: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-29-2020 13:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 13:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-29-2020 13:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-29-2020 13:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NEGATIVE	Initial Entry

090177e196ae30a3\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: 1011181

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
Oct-29-2020 13:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-29-2020 13:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-29-2020 13:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-29-2020 13:59:08 (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-29-2020 13:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.g Hopkins)	Data Entry: YES Date of Collection: Oct/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-29-2020 13:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.g Hopkins)	Data Entry: Sample ID: BR2VM0	Initial Entry

090177e196ae30a3\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: 10111181

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 13:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gail Hopkins (pfe.ghopkins)	Data Entry: BR2VM0	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1011

Subject No: 1011181

Generated By: pfe.levissc

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
Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Not Done	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Not Done	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Not Done	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-29-2020 17:52:10 (UTC-05:00) Eastern	ACV0PFEINFP6000	Rachel Pierce	Data Entry: Not Done	Initial Entry

090177e196ae30a3\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: 1011181

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

Time (US & Canada)		(pfe.spierce)	
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7. Route:

Date	Location	User	Value	Reason
Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Not Done	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 17:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Not Done	Initial Entry

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 1011181

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-02-2020 13:27:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 1: Closed	Response satisfies query
Dec-01-2020 15:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Query 1: Answered	Added toothache to AE
Dec-01-2020 15:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 1: Opened	Per source, subject had toothache. Please review and add to AE CRF, otherwise clarify.
Dec-01-2020 13:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Dec/1/2020	Initial Entry

090177e196ae30a3\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: 10111181

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
Dec-01-2020 13:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-01-2020 13:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-01-2020 13:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-01-2020 13:28:03 (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.
Dec-01-2020 13:28:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspan)	Data Entry: YES Date of Collection: Dec/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-01-2020 13:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspan)	Data Entry: Sample ID: BRGCLW	Initial Entry

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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: 1011181

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-01-2020 13:28:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	Data Entry: BRGCLW	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-01-2020 13:28:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	Data Entry: Sample ID: BRGCLY	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-01-2020 13:28:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	Data Entry: BRGCLY	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-01-2020 13:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	Data Entry: Sample ID: BRGCLX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-01-2020 13:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	Data Entry: BRGCLX	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-01-2020 13:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	Data Entry: Sample ID: BGVV28	Initial Entry

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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: 1011181

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Dec-01-2020 13:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	Data Entry: BGVV28	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-01-2020 13:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	Data Entry: Sample ID: BGVV29	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Dec-01-2020 13:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Holly Spain (pfe.hspain)	Data Entry: BGVV29	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Form Created	

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

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
Nov-02-2020 09:54:33 (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: 10111181

Generated By: pfe.levisse

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
Dec-01-2020 15:23:46 (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: 1011181

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Tingling around the mouth	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Oct/8/2020 15:15	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO End Date Time: Oct/8/2020 16:14	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1011

Subject No: 1011181

Generated By: pfe.levisse

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Form Status: Data Complete, Locked, Frozen

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

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

Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-11-2020 10:12:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 2: Closed	Response satisfies query
Nov-11-2020 08:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Query 2: Answered	This AE will stay, will update the other AE once unlocked.
Nov-10-2020 22:04:47	ACV0PFEINFP6000	Ute Frantz	Query 2: Opened	Only one primary

090177e196ae30a3\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:** 10111181**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1011) Clinical Research Consulting, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

(UTC-05:00) Eastern Time (US & Canada)		(pfe.frantu)		Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Nov-10-2020 22:04:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	issued in error
Nov-10-2020 21:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Opened	Only one primary Adverse Event should be chosen to have question 'Did the adverse event cause the subject to be discontinued from the study?' answered as YES if applicable. Please chose Primary Adverse Event.
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Locked, Frozen

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

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Subject Initials: ---

Generated By: pfe.levisse

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

Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-02-2020 09:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Tingling at finger tips	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Oct/8/2020 15:15	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO End Date Time: Oct/8/2020 16:15	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae30a3\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: 1011181

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

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

Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 00:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 2: Closed	Response satisfies query
Nov-11-2020 15:49:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	changed information due to Sponsor instructions
Nov-11-2020 15:49:58	ACV0PFEINFP6000	Rachel Pierce	Data Entry:	changed information

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Header Text: c4591001				
Visit: Logs - Unscheduled		Form: ADVERSE EVENT REPORT - eCRF Audit Trail History		
Form Version: 22-Apr-2020 21:02		Form Status: Data Complete, Locked, Frozen		
Site No: 1011		Site Name: (1011) Clinical Research Consulting, LLC		
Subject No: 1011181		Subject Initials: ---		
Generated By: pfe.levisse		Generated Time (GMT): 29-Mar-2021 04:21		
(UTC-05:00) Eastern Time (US & Canada)		(pfe.spierce)	NOT APPLICABLE	due to Sponsor instructions
Nov-11-2020 10:13:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 2: Reissued:Opened	DM Q: Page is unlocked and unfrozen. Please update.
Nov-11-2020 08:29:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Query 2: Answered	page is locked, unable to change
Nov-10-2020 22:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Opened	Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.
Nov-10-2020 22:05:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	issued in error
Nov-10-2020 21:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Opened	Only one primary Adverse Event should be chosen to have question 'Did the adverse event cause the subject to be discontinued from the study? answered as YES if applicable. Please chose Primary Adverse Event.
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: DRUG WITHDRAWN	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1011

Subject No: 10111181

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-02-2020 09:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

Subject Initials: ---

Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Toothache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Oct/30/2020 09:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO End Date Time: Nov/17/2020 09:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1011

Subject No: 1011181

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1011) Clinical Research Consulting, LLC

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Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-04-2020 01:52:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Dec-03-2020 08:08:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 08:08:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify:	Transcription Error

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Header Text: c4591001

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Site No: 1011

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Generated By: pfe.levisse

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Form Status: Data Complete, Frozen

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			tooth ache	
Dec-02-2020 11:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Tooth ache is listed as related to study Vaccine. Please confirm causality assessment and clarify what concomitant treatment was given.
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1011) Clinical Research Consulting, LLC

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Dec-01-2020 15:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	<u>Data Entry:</u> NO	Initial Entry

Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1011**Site Name:** (1011) Clinical Research Consulting, LLC**Subject No:** 10111181**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-12-2020 01:31:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe mahadp07)	Query 1: Closed	Closed as data updated.
Nov-11-2020 15:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	date undated due to Sponsor instructions.
Nov-11-2020 15:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Oct/8/2020	date undated due to Sponsor instructions.
Nov-10-2020 21:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe frantu)	Query 1: Opened	The discontinuation date of 29OCT2020 should be relative to the AE causing the the withdrawal of the study vaccine, AE start 08OCT2020 and end 08OCT2020. Please adjust Discontinuation date.
Oct-29-2020 17:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Oct/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-29-2020 17:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1011**Site Name:** (1011) Clinical Research Consulting, LLC**Subject No:** 1011181**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

Nov-02-2020 12:26:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 3: Closed	Response satisfies query
Nov-02-2020 10:02:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Query 3: Answered	Changed data per query
Oct-30-2020 13:43:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 3: Reissued:Opened	Please confirm as no AE is entered.
Oct-30-2020 13:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Keri Clarke (pfe.clarkek2)	Query 2: Closed	Response satisfies query
Oct-30-2020 08:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Query 3: Answered	entering now
Oct-30-2020 08:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Oct-30-2020 08:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	changed information due to instructions in query
Oct-30-2020 08:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: ADVERSE EVENT	changed information due to instructions in query
Oct-30-2020 08:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Keri Clarke (pfe.clarkek2)	Query 2: Opened	ClinQuery: the deleted text in the specify box stated that subject was withdrawn due to an AE. Please add

Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1011**Site Name:** (1011) Clinical Research Consulting, LLC**Subject No:** 10111181**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

				details of the AE to the AE log CRF and consider if the reason for withdrawal subject be updated to Adverse Event.
Oct-29-2020 17:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-29-2020 17:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is PHYSICIAN DECISION but "Specify Status" is Provided.
Oct-29-2020 17:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: PHYSICIAN DECISION	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Oct-29-2020 17:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry:	Transcription Error
Oct-29-2020 17:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rachel Pierce (pfe.spierce)	Data Entry: Subject experienced AE after VAX #1.PI decided to not allow subject to receive VAX#2	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 16:46:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Feb/2/2021	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1011

Subject No: 10111181

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

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 - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-04-2021 16:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 16:47:00 (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.
Feb-04-2021 16:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae30a3\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: 10111181

Generated By: pfe.levissc

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-04-2021 16:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: Feb/2/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-04-2021 16:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Linda Welch (pfe.lwelch)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae30a3\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: 1011181

Generated By: pfe.levissc

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-30-2020 08:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	changed information due to instructions in query
Oct-29-2020 17:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-08-2020 23:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-08-2020 16:13:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-11-2020 15:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/8/2020	date undated due to Sponsor instructions.
Oct-30-2020 08:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/29/2020	changed information due to instructions in query
Oct-29-2020 17:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/29/2020	Initial Entry
Oct-08-2020 23:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/8/2020	Initial Entry
Oct-08-2020 16:13:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/8/2020	Initial Entry

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1011

Site Name: (1011) Clinical Research Consulting, LLC

Subject No: 10111181

Subject Initials: ---

Generated By: pfe.levissc

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-10-2020 12:04:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Susann Varano (pfe.svarano)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae30a3\Final\Final On: 01-Apr-2021 04:11 (GMT)