

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/9/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10121163]
2.	Birth Date:	(b) (6) 1979
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/9/2020
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: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergic Atopic Dermatitis]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Penicillin Allergy (Anaphylactic Shock)]
	Start Date:	UNK/UNK/1984
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Codeine Allergy]
	Start Date:	UNK/UNK/1984
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Iodine Allergy]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cat Scratch Disease]
	Start Date:	UNK/UNK/1982
	Ongoing:	YES

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/9/2020
2.	Weight:	[139.0]
3.	Unit:	LB
4.	Height:	[69.0]
5.	Unit:	in
6.	Body Mass Index:	[20.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

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:	Sep/9/2020
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:	

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/9/2020
2.	Randomization Number:	[85512]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

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: Sep/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPL1VT]
5.b	Sample ID	[BPL1VV]
5.c	Sample ID	[BPL1VW]
5.d	Sample ID	[BP43XW]

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

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: Sep/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP43XV]
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090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

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:	Sep/9/2020 16:58
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

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

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
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 20-Feb-2021 02:16

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

Vital Signs

1.	Date:	//
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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:	

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

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: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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?	

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

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: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

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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090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

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: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

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: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

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: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

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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090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Sep/16/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
----	-------------------------	---------

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Sep/16/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Sep/16/2020
2.	Date of First Symptom Started:	Sep/11/2020
3.	Symptoms Ongoing?	YES

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	YES
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Sep/16/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings/Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Visit not done per protocol. PD has been created]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Visit not done per protocol. PD created]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Sep/16/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121163**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Form Comments](#)[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST	
	Occurrence of Visits or Contacts:	NO	Comments
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM	
	Occurrence of Visits or Contacts:	NO	Comments
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN	
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]	Comments
1.d	Physician or Healthcare Professional:	URGENT CARE	
	Occurrence of Visits or Contacts:	NO	Comments
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION	
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]	Comments
1.f	Physician or Healthcare Professional:	OTHER	
	Occurrence of Visits or Contacts:	NO	Comments

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO	Comments
----	--	----	--------------------------

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Sep/16/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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

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Respiratory Treatment

1.	What is the treatment Identifier?	[]
2.	Concomitant Non-drug Treatment Pre-specified:	
3.	Treatment:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Sep/16/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS	Comments
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO	Comments
3.	Toxicity Grade:	2	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE
Sep/16/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test :	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Sep/16/2020

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Sep/16/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Sep/16/2020

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Sep/16/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS
Sep/16/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Sep/16/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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.	Start Date:	//
6.	Ongoing?	

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Sep/16/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
----	-------------------------	--

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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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090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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

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Disposition - Treatment

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Oct/17/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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

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: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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	LEFT UPPER ARM DERMATITIS AT INJECTION SITE	Sep/11/2020 UNK:UNK	YES	Repeating Pages
2. DELETED	ADVERSE EVENT	2	SHORTNESS OF BREATH	Sep/11/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	INSOMNIA	Sep/12/2020 UNK:UNK	YES	Repeating Pages
4.	ADVERSE EVENT	4	WEIGHT LOSS	Sep/14/2020 UNK:UNK	NO End Date Time: Oct/4/2020 UNK: UNK	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[LEFT UPPER ARM DERMATITIS AT INJECTION SITE]
4.	Start Date Time:	Sep/11/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[SHORTNESS OF BREATHE]
4.	Start Date Time:	Sep/11/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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
12.	Was a Non-Drug Treatment given?	NO

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1012) HOPE Research Institute

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)	[INSOMNIA]
4.	Start Date Time:	Sep/12/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[WEIGHT LOSS]
4.	Start Date Time:	Sep/14/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/4/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[Back to Form](#)

Medication Error

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

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Date:	//

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[Back to Form](#)

Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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:	

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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?	

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (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: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Not Applicable _____ //	Comments
2.	Primary Reason for Unblinding:	Not Applicable _____	Comments

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	Sep/24/2020
----	------------------------------	-------------

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: DEATH DETAILS CODED

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Death Details

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	Comments
----	---	-------------------------------	--------------------------

Cause of Death

2.	Cause of Death Status:	Not Applicable _____
	Cause of Death:	Not Applicable _____ []

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1012) HOPE Research Institute

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/17/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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
- CRF_Sign_1

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-10-2020 18:42:24 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject qualified for enrollment Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Sep/16/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit entry being done to capture shortness of breath reported during a phone call on 9/16/2020. Not an actual possible covid illness visit. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Sep/16/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit entry being done to capture shortness of breath reported during a phone call on 9/16/2020. Not an actual possible covid illness visit. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Sep/16/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
2	Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit entry being done to capture shortness of breath reported during a phone call on 9/16/2020. Not an actual possible covid illness visit. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
3	Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit entry being done to capture shortness of breath reported during a phone call on 9/16/2020. Not an actual possible covid illness visit. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Sep/16/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
4	Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit entry being done to capture shortness of breath reported during a phone call on 9/16/2020. Not an actual possible covid illness visit. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
5	Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit entry being done to capture shortness of breath reported during a phone call on 9/16/2020. Not an actual possible covid illness visit. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Sep/16/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
6	Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit entry being done to capture shortness of breath reported during a phone call on 9/16/2020. Not an actual possible covid illness visit. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
7	Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit entry being done to capture shortness of breath reported during a phone call on 9/16/2020. Not an actual possible covid illness visit. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Sep/16/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
8	Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit entry being done to capture shortness of breath reported during a phone call on 9/16/2020. Not an actual possible covid illness visit. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Sep/16/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
9	Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit entry being done to capture shortness of breath reported during a phone call on 9/16/2020. Not an actual possible covid illness visit. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - Comments
Sep/16/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
Form	Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
Form	Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit missed ----- Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
1.a	Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
1.a	Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit missed <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
1.b	Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
1.b	Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit missed Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
1.c	Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
1.c	Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit missed ----- Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
1.d	Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
1.d	Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit missed Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
1.e	Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
1.e	Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit missed <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
1.f	Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
1.f	Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit missed Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
2	Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
2	Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit missed <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
3	Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
3	Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit missed Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - Comments
Sep/16/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
Form	Nov-09-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
Form	Nov-05-2020 17:08:33 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit not done. CRF completed to capture cough which cannot be added to AE log. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
1	Nov-09-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
1	Nov-05-2020 17:08:33 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit not done. CRF completed to capture cough which cannot be added to AE log. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
2	Nov-09-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
2	Nov-05-2020 17:08:33 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit not done. CRF completed to capture cough which cannot be added to AE log. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
3	Nov-09-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	
3	Nov-05-2020 17:08:33 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Visit not done. CRF completed to capture cough which cannot be added to AE log. <hr/> Not Done

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Oct-06-2020 13:00:05 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
1	Oct-06-2020 13:00:05 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
2	Oct-06-2020 13:00:05 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Oct-06-2020 13:00:17 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
1	Oct-06-2020 13:00:17 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Stephanie Catanzaro	N/A	Feb-24-2021 12:13:36 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Matthew Doust	Approved	Nov-12-2020 13:39:48 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
---------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, MatthewDoust, 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.

Selma Leudtke	N/A	Nov-11-2020 16:43:00 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Matthew Doust	Approved	Nov-11-2020 08:08:21 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
---------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, MatthewDoust, 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.

Sahara Vega	N/A	Nov-03-2020 14:45:47 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

Affidavit:

N/A

Matthew Doust	Approved	Oct-30-2020 12:18:09 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MatthewDoust, 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.

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

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
Sep-10-2020 12:32:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 12:32:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-10-2020 12:32:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: OBTAINED Date Written Consent Obtained Sep/9/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-10-2020 12:32:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10121163	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-10-2020 12:32:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1979	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-10-2020 12:32:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-10-2020 12:32:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 12:32:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: WHITE	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 06:12:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Closed	As per site response
Oct-06-2020 11:18:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Subject withdrew consent on 9/24/2020.
Oct-05-2020 22:51:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Details on visit 'V2VX2L' are missing. Kindly consider to update or else clarify. Thank you.
Sep-10-2020 18:42:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sep/9/2020	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

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
Sep-10-2020 18:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sep/9/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-10-2020 18:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-10-2020 18:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: COMPLETED	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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I.a

Date	Location	User	Value	Reason
Sep-16-2020 16:49:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History: Allergic Atopic D Term: ermatitis Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:49:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 11:45:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gary Steven Friedman (pfe.friedg01)	Query 2: Closed	Response satisfies query
Sep-30-2020 11:42:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gary Steven Friedman (pfe.friedg01)	Query 1: Closed	Response satisfies query
Sep-29-2020 16:54:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	Subject is using topical medication only
Sep-29-2020 16:54:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 2: Answered	Subject is using topical medication only
Sep-29-2020 12:36:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gary Steven Friedman (pfe.friedg01)	Query 2: Opened	QUERY OUTSTANDING X 7 days: please address. Thank you.
Sep-22-2020 07:33:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gary Steven Friedman (pfe.friedg01)	Query 1: Opened	ATOPIC DERMATITIS (ONGOING): please confirm the participant IS or IS NOT receiving

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.lewissc

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

				ORAL CORTICOSTEROIDS or ORAL OR PARENTERAL IMMUNOMODULATORS currently.
Sep-16-2020 16:49:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Allergic Atopic Dermatitis	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 16:49:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: UNK/UNK/2016	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 16:49:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Sep-16-2020 16:51:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Penicillin Allergy (Anaphylactic Shock) Start Date: UNK/UNK/1984 Ongoing: YES	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:51:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Penicillin Allergy (Anaphylactic Shock)	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: UNK/UNK/1984	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 16:51:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-21-2020 15:10:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Line/MH Number: 3 Medical History Term: Codeine Allergy Start Date: UNK/UNK/1984 Ongoing: YES	Transcription Error
Sep-17-2020 09:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Line/MH Number: 3 Medical History Term: Codeine Allergy Start Date: UNK/UNK/1984	Changed Information

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

			Ongoing: YES	
Sep-16-2020 16:52:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 3 mber: Medical Hist Codeine Allergy (ory Term: Hallucinations) Start Date: UNK/UNK/1984 Ongoing: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:52:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 03:17:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 2: Closed	Response satisfies query
Sep-21-2020 15:10:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Sep-21-2020 15:10:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Codeine Allergy	Transcription Error
Sep-21-2020 11:30:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 2: Opened	DM: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Sep-17-2020 11:27:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Sep-17-2020 09:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1012**Subject No:** 10121163**Generated By:** pfe.lewissc**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1012) HOPE Research Institute**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

Sep-17-2020 09:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Codeine Allergy	Changed Information
Sep-17-2020 03:32:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term CODEINE ALLERGY (HALLUCINATIONS). Split the term into CODEINE ALLERGY and DRUG INDUCED HALLUCINATIONS and submit separately. Thank you.
Sep-16-2020 16:52:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Codeine Allergy (Hallucinations)	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 16:52:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: UNK/UNK/1984	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 16:52:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-17-2020 09:18:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Line/MH Number: 4 Medical History Term: Iodine Allergy Start Date: UNK/UNK/2017 Ongoing: YES	Changed Information

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

Sep-16-2020 16:53:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 4 mber: Medical Hist Iodine Allergy (Res ory Term: piratory, Sneezing) Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry
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090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:53:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 11:27:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Sep-17-2020 09:18:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-17-2020 09:18:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Iodine Allergy	Changed Information
Sep-17-2020 03:32:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term IODINE ALLERGY (RESPIRATORY, SNEEZING). Split the term into IODINE ALLERGY and RESPIRATORY, SNEEZING and submit separately. Thank you.
Sep-16-2020 16:53:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Iodine Allergy (Respiratory, Sneezing)	Initial Entry

I.d Start Date:

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Sep-16-2020 16:53:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: UNK/UNK/2017	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 16:53:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-16-2020 16:54:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Cat Scratch Disease Start Date: UNK/UNK/1982 Ongoing: YES	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 16:54:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 16:54:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Cat Scratch Disease	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 16:54:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: UNK/UNK/1982	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 16:54:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sep/9/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 139.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 69.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20.5	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

7.a

Date	Location	User	Value	Reason
Sep-10-2020 18:45:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Record Identifier:: 1 Temperature: 97.7 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 97.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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
Sep-10-2020 18:45:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sep/9/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-10-2020 18:45:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-10-2020 18:45:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Sep-10-2020 18:45:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NEGATIVE	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-10-2020 18:45:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sep/9/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-10-2020 18:45:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 85512	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: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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
Sep-10-2020 18:45:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 18:45:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-13-2020 14:46:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-11-2020 02:14:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 18:45:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 18:45:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (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: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-13-2020 14:46:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: BPL1VT	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-13-2020 14:46:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BPL1VT	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-13-2020 14:46:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: BPL1VV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-13-2020 14:46:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BPL1VV	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-13-2020 14:46:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: BPL1VW	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-13-2020 14:46:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BPL1VW	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-06-2020 17:16:28 (UTC-07:00) Mountain	ACV0PFEINFP6000	Sahara Vega	Data Entry: Sample ID: BP43XW	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (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: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

Time (US & Canada)		(pfe.svega)		
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5.d Sample ID

Date	Location	User	Value	Reason
Oct-06-2020 17:16:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BP43XW	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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
Sep-10-2020 18:46:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 18:46:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-13-2020 12:11:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-11-2020 02:11:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 18:46:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 18:46:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (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: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-13-2020 12:11:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: BP43XV	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-13-2020 12:11:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BP43XV	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

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
Sep-10-2020 18:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 18:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-10-2020 18:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-10-2020 18:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sep/9/2020 16:58	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 18:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-10-2020 18:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: LEFT	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 18:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 18:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 18:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

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
Sep-10-2020 18:48:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO - REACTOGENICITY E-DIAR Y NOT COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-06-2020 01:14:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 3: Closed	Response satisfies query
Nov-05-2020 17:08:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 3: Answered	Changed data per query
Nov-05-2020 02:03:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Usha Ogirala (pfe.ogirau)	Query 1: Closed	Response satisfies query
Nov-05-2020 01:08:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Usha Ogirala (pfe.ogirau)	Query 3: Reissued:Opened	DM1: Kindly review and complete 'Illness Details form' at this visit. Thank you.
Nov-04-2020 16:40:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 3: Answered	Changed data per query
Nov-04-2020 16:39:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Changed data per query
Nov-04-2020 03:23:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-04-2020 03:18:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 3: Opened	DM: Kindly review and complete 'Health Care Utilization, Illness Details form' at this visit. Thank you.
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Sep/16/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121163**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21

Nov-03-2020 14:48:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-03-2020 14:48:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-03-2020 14:48:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sep/16/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-03-2020 14:48:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121163**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**I. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-26-2021 18:29:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Closed	late entry uploaded in chart noted.
Feb-25-2021 13:31:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	This has been uploaded.
Feb-24-2021 23:22:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Opened	Unable to verify, please provide source
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sep/16/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sep/11/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 22:33:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Azeemuddin Mohammed (pfe.mohaa117)	Query 1: Closed	Response satisfies query
Feb-24-2021 12:02:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	This symptoms are still ongoing.
Feb-15-2021 04:15:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ashwini Devi Subhash (pfe.subhaa)	Query 1: Opened	Please confirm the symptoms are still ongoing for this COVID illness. If all symptoms for this illness are resolved; please update the Last Symptoms

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Generated By: pfe.lewissc

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				Resolved Date else clarify.
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms: NEW OR INCREASE D COUGH Symptom Present: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptom NEW OR INCREASED s: SHORTNESS OF BREA TH Symptom YES Present:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NEW OR INCREASED SHORTNES S OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms: CHILLS	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

			Symptom Present: NO	
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4.d Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57	ACV0PFEINFP6000	Sahara	Data Entry:	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121163**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

(UTC-07:00) Mountain Time (US & Canada)		Vega (pfe.svega)	Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	
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4.f Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

4.h

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1012

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Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 14:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Sep/16/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Sep/16/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levisse

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

7. Test Result:

Date	Location	User	Value	Reason
Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-03-2020 14:50:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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
Nov-04-2020 16:39:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-04-2020 16:39:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 16:39:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 16:39:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Visit not done per protocol. PD has been created	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

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
Nov-04-2020 16:39:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-04-2020 16:39:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 16:39:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 16:39:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Visit not done per protocol. PD create d	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/16/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

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I.a

Date	Location	User	Value	Reason
Feb-24-2021 12:13:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: NO	Subject talked on the phone with specialist but did not have an actual visit with them.
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts:	Initial Entry
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: Not Done	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-26-2021 18:22:09 (UTC-07:00) Mountain	ACV0PFEINFP6000	Aloma Ratnasoma	Query 1: Closed	verified

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/16/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121163**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

Time (US & Canada)		(pfe.ratnaa05)		
Feb-25-2021 13:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	This has been uploaded.
Feb-24-2021 23:20:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Reissued:Opened	The response not is not in the source. please provide for verification purposes.
Feb-24-2021 12:13:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Subject talked on the phone with specialist but did not have an actual visit with them.
Feb-24-2021 12:13:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Subject talked on the phone with specialist but did not have an actual visit with them.
Feb-22-2021 15:38:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Opened	source unavailable to verify the data, please revisit and update if available
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry:	Initial Entry
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

I.b

Date	Location	User	Value	Reason
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/16/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121163**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21

			Occurrence of Visits or Co NO ntacts:	
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Do ne Occurrence of Visits or Co ntacts:	Initial Entry
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Do ne Occurrence of Visits or Co Not Do ntacts: ne	Initial Entry

I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry:	Initial Entry
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

I.c

Date	Location	User	Value	Reason
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitio Not Done ner:	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/16/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121163**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21

			Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts:	Initial Entry
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: Not Done	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry:	Initial Entry
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/16/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121163**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21

Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: NO	Initial Entry
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts:	Initial Entry
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: Not Done	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry:	Initial Entry
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

1.e

Date	Location	User	Value	Reason
Feb-24-2021 12:13:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Type of Practitioner: Not Done	Changed Information

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/16/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

			Number of Occurrences of Visits or Contacts: YES Number of Visits or Contacts: 1	
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: NO	Initial Entry
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts:	Initial Entry
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Contacts: Not Done	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/16/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-24-2021 12:13:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Changed Information
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry:	Initial Entry
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

I.f

Date	Location	User	Value	Reason
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Co ntacts: NO	Initial Entry
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done Occurrence of Visits or Co ntacts:	Initial Entry
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: Not Done	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/16/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

			Occurrence of Visits or Contacts:	Not Done
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If Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> Not Done	Initial Entry

If Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-09-2020 14:10:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_HOHCU002_01
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/16/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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If Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry : NO	Initial Entry
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry :	Initial Entry
Nov-06-2020 02:21:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ashwini Devi Subhash (pfe.subhaa)	Query 1: Rei ssued: Opene d	DM: Per CCG 8.35, this is a required CRF. If subject didn't utilize any of the listed healthcare services, complete the form with answering as "No". Provide appropriate answers to each question asked even if subject didn't utilize healthcare services.
Nov-05-2020 17:06:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Ans wered	Original value is correct
Nov-05-2020 05:05:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW5289640;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Nov-04-2020 16:39:56 (UTC-07:00) Mountain	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry : Not D	Initial Entry

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/16/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

Time (US & Canada)			one	
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2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry:	Initial Entry
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 14:11:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1 : Closed	Auto closed by Validation Check: VC_HOHCU002_02
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Answered	Initial Entry
Nov-09-2020 09:26:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry
Nov-09-2020 09:24:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry:	Initial Entry
Nov-06-2020 02:19:29 (UTC-07:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1 : Opened	DMW5289683;Response to 'Has the subject been hospitalized due to

090177e196ae401c\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Sep/16/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

Generated By: pfe.levissc

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

Mountain Time (US & Canada)				potential COVID-19 illness?' is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Nov-04-2020 16:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Sep/16/2020**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121163**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**I. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-09-2020 11:40:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Closed	Response satisfies query
Nov-09-2020 09:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Changed data per query
Nov-09-2020 09:29:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry
Nov-09-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry:	Initial Entry
Nov-07-2020 07:17:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Opened	CLINQUERY: Per CCG, this form is a required CRF. Please complete as appropriate. If Diagnosis is not obtained, answer the question as "NO" in CRF and enter toxicity grade between 1-5 in per CCG section 8.33.5 in relation to reported symptoms.
Nov-05-2020 17:08:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-09-2020 09:29:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
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Nov-09-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry:	Initial Entry
Nov-05-2020 17:08:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-09-2020 09:29:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: 2	Initial Entry
Nov-09-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry:	Initial Entry
Nov-05-2020 17:08:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1012

Subject No: 10121163

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-06-2020 11:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sep/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-06-2020 11:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-09-2020 23:27:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 2: Closed	Response satisfies query
Oct-09-2020 15:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-09-2020 15:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Oct-09-2020 15:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Oct-09-2020 15:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: ADVERSE EVENT	Changed Information
Oct-08-2020 07:54:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 2: Opened	DM: The Adverse Event Action Taken is DRUG WITHDRAWN but reason for treatment discontinuation is not reported as ADVERSE EVENT

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

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				or DEATH. Please review and clarify.
Oct-06-2020 11:48:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-06-2020 11:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is WITHDRAWAL BY SUBJECT but "Specify Status" is missing.
Oct-06-2020 11:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: WITHDRAWAL BY SUBJECT	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Oct-09-2020 15:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry:	Changed Information
Oct-06-2020 11:48:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Due to AE related to vaccine #1 subject withdrew consent.	Initial Entry

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Header Text: c4591001

Visit: Follow-Up - Unscheduled

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I. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-30-2020 01:33:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 1: Closed	Response satisfies query
Oct-29-2020 22:45:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 2: Closed	Response satisfies query
Oct-29-2020 17:35:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	Withdrew consent 9/24/2020. Willing to speak with site after for follow-up. Last date of contact 10/17/2020.
Oct-29-2020 17:34:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Yes last date of contact 10/17/2020
Oct-29-2020 05:55:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 2: Reissued:Opened	Withdrawal of consent 24Sep20 is before date of completion 20Oct20. Kindly verify both the dates and update the last contact date of subject here. Thank you.
Oct-29-2020 05:54:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 1: Reissued:Opened	Kindly verify and confirm entered date 17Oct20 is the last day of contact to subjects if yes confirm via query response or else update CRF. Thank you.
Oct-28-2020 16:31:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	Data has been changed to reflect last date site spoke with subject regarding AE follow-up
Oct-28-2020 16:31:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Completion/Discontinuation /Death on the Follow-Up Disposition form is after "Withdrawal of consent" date. Please review and correct as appropriate.

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Subject No: 10121163
Generated By: pfe.levissc

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Oct-28-2020 16:31:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-28-2020 16:31:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Oct/17/2020	New Information
Oct-27-2020 13:46:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe frantu)	Query 1: Reissued:Opened	Thank you for your response. Please note the End of Study date must be the last date of contact with the subject. As you noted it was 06 OCT 2020, please consider updating the Follow up End of Study date to this last date of Contact with Subject.
Oct-27-2020 12:17:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Written WOC provided 9/24/2020. Site contacted subject on 10/6/2020 to get end date since she was willing to speak with us post WOC. Date will remain the same.
Oct-24-2020 06:04:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Opened	Adverse Event Weight Loss resolved on 04-Oct-2020, but disposition follow up date is recorded as 24-Sep-2020. Please confirm whether the subject was contacted on 04-Oct-2020. If yes, please consider updating the disposition date in this CRF. Else clarify
Oct-14-2020 12:03:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sep/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-14-2020 12:03:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

Header Text: c4591001

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Subject No: 10121163

Generated By: pfe.levissc

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Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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3. Status:

Date	Location	User	Value	Reason
Oct-14-2020 12:03:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: ADVERSE EVENT	Initial Entry

Header Text: c4591001

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Generated By: pfe.levisse

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Form Status:

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Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Created	

Header Text: c4591001

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Nov-03-2020 14:45:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Deleted	Changed Information
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Created	

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Subject No: 10121163

Generated By: pfe.levissc

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Date	Location	User	Value	Reason
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Created	

Header Text: c4591001

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Subject No: 10121163

Generated By: pfe.levissc

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Date	Location	User	Value	Reason
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Created	

Header Text: c4591001

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Site Name: (1012) HOPE Research Institute

Subject No: 10121163

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-18-2020 18:36:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchemo (pfe.banchp)	Query 1: Closed	Response satisfies query
Oct-17-2020 11:56:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-17-2020 11:56:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: LEFT UPPER ARM DERMATITIS AT INJECTION SITE	Changed Information
Oct-14-2020 19:02:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchemo (pfe.banchp)	Query 1: Reissued:Opened	GPDCLIN: Thank you for your response. Please confirm if dermatitis is located at injection site. If yes please consider updating the verbatim term as applicable, or clarify.
Oct-14-2020 12:01:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-14-2020 12:01:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: LEFT UPPER ARM DERMATITIS	Changed Information

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Oct-11-2020 08:31:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (pfe.banchp)	Query 1: Opened	GPDCLIN: Please review and consider updating to include dermatitis location. Thank you.
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: DERMATITIS	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sep/11/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-29-2020 23:39:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Malla Reddy Chevella (pfe.chevem01)	Query 2: Closed	Response satisfies query
Oct-29-2020 17:38:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	End of study is 10/17/2020 which is the last contact date made with subject. AE will remain as ongoing.
Oct-29-2020 05:57:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 2: Reissued:Opened	End of study 20Oct20 is entered but AE is still ongoing. Kindly verify and confirm the status of AE and update CRF or else confirm. Thank you.
Oct-28-2020 16:32:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	Original value is correct
Oct-28-2020 16:31:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please

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				review and update as appropriate.
Oct-23-2020 13:14:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Oct-23-2020 12:23:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	This is left ongoing because it is ongoing at this time.
Oct-18-2020 05:10:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	S Vijaya Kumar (pfe.kumas557)	Query 1: Reissued:Opened	DM Re-query: 'Disposition Follow-up form is completed and this Adverse Event is still reported as ongoing. Kindly review and update Ongoing as appropriate and respond to this query.
Oct-17-2020 11:56:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Changed data per query
Oct-15-2020 06:42:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Reissued:Opened	DM: Per query provided response, please update database accordingly as 'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Thank you.
Oct-14-2020 12:04:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Changed data per query
Oct-14-2020 12:03:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.

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Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 09:56:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: DRUG WITHDRAWN	Transcription Error

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Nov-11-2020 23:34:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe mahadp07)	Query 2: Closed	Closed as data updated.
Nov-11-2020 16:43:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Response to query
Nov-11-2020 16:43:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NOT APPLICABLE	Response to query
Nov-10-2020 20:07:09 (UTC-07:00) Mountain 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 20:06:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe frantu)	Query 1: Closed	issued in error
Nov-10-2020 19:19:29 (UTC-07:00) Mountain 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.
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: DRUG WITHDRAWN	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-06-2020 13:02:04	ACV0PFEINFP6000	Sahara	Data Entry:	Initial Entry

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(UTC-07:00) Mountain Time (US & Canada)		Vega (pfe.svega)	NO	
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 12:03:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-10-2020 04:55:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	DM: 'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as 'ADVERSE EVENT'. Please review and update as appropriate. Thank you.
Oct-09-2020 15:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION -

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Subject No: 10121163

Generated By: pfe.levissc

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				FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-08-2020 06:27:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	DM: 'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as 'ADVERSE EVENT'. Please review and update as appropriate. Thank you.
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-06-2020 13:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Initial Entry

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Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-06-2020 13:03:04 (UTC-07:00) Mountain 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-03-2020 19:34:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Closed	Response satisfies query
Nov-03-2020 14:45:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-31-2020 13:13:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Reissued:Opened	Clin: Please move this event to the potential COVID-19 Illness Visit SOD CRF form (should no be on the AE form) and enter all the information available. Please provide the reason why a nasal swab was not collected
Oct-27-2020 12:06:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Thank you. PD has been created for missed visit.
Oct-25-2020 13:59:29	ACV0PFEINFP6000	Salim	Query 1: Reissued:Opened	Clin: Per protocol

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(UTC-07:00) Mountain Time (US & Canada)		Bouguermouh (pfe.bogus)		section 8.13., SHORTNESS OF BREATH do not overlap with specific systemic events (ie, fever, chills, new or increased muscle pain, diarrhea, vomiting) should have please triggered a COVID-19 visit and captured only on the SOD form
Oct-23-2020 11:58:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	This was assessed as related to vaccine and not possible covid which did not require triggering in this instance.
Oct-18-2020 16:51:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Opened	Clin: Per protocol section 8.1., COVID-19 listed symptom SHORTNESS OF BREATH, not a specific systemic event, should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance.
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: SHORTNESS OF BREATHE	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sep/11/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

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Date	Location	User	Value	Reason
Oct-30-2020 07:25:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 2: Closed	Closed as per site response.
Oct-29-2020 17:38:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	End of study is 10/17/2020 which is the last contact date made with subject. AE will remain as ongoing.
Oct-29-2020 05:57:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 2: Reissued:Opened	End of study 20Oct20 is entered but AE is still ongoing. Kindly verify and confirm the status of AE and update CRF or else confirm. Thank you.
Oct-28-2020 16:33:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	AE is ongoing no further action
Oct-28-2020 16:31:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Oct-18-2020 22:09:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Oct-17-2020 11:57:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	AE remains ongoing as of 10/17/2020
Oct-15-2020 06:43:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Reissued:Opened	DM: Per query provided response, please update database accordingly as 'Disposition Follow-up form is completed and this Adverse Event is

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				still ongoing. Thank you.
Oct-14-2020 12:04:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Changed data per query
Oct-14-2020 12:03:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Initial Entry

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 23:29:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 2: Closed	Response satisfies query
Oct-09-2020 15:31:08 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query

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Time (US & Canada)				
Oct-09-2020 15:31:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-09-2020 15:31:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Changed Information
Oct-07-2020 06:14:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Opened	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-07-2020 06:09:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 2: Reissued:Opened	DM 1: More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes', please review and update as appropriate, thank you.
Oct-06-2020 13:05:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	Original value is correct
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'.
Oct-06-2020 13:03:04 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be

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Time (US & Canada)				discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-06-2020 13:03:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Initial Entry

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1. Category:

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Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: INSOMNIA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sep/12/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-30-2020 07:25:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 2: Closed	Closed as per site response.
Oct-29-2020 17:38:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	End of study is 10/17/2020 which is the last contact date made with subject. AE will remain as ongoing.
Oct-29-2020 05:57:40	ACV0PFEINFP6000	Sandip	Query 2: Reissued:Opened	End of study

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(UTC-07:00) Mountain Time (US & Canada)		Namdeorao Suryawanshi (pfe.suryas18)		20Oct20 is entered but AE is still ongoing. Kindly verify and confirm the status of AE and update CRF or else confirm. Thank you.
Oct-28-2020 16:34:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	AE is ongoing, no further action
Oct-28-2020 16:31:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Oct-18-2020 22:11:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Oct-17-2020 11:58:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	AE remains ongoing as of 10/17/2020
Oct-15-2020 06:43:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Reissued:Opened	DM: Per query provided response, please update database accordingly as 'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Thank you.
Oct-14-2020 12:04:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Original value is correct
Oct-14-2020 12:03:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.

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Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 17:44:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query

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Header Text: c4591001 Visit: Logs - Unscheduled Form Version: 22-Apr-2020 21:02 Site No: 1012 Subject No: 10121163 Generated By: pfe.levissc				
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History Form Status: Data Complete Site Name: (1012) HOPE Research Institute Subject Initials: --- Generated Time (GMT): 29-Mar-2021 04:21				
Nov-12-2020 09:56:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-12-2020 09:56:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NOT APPLICABLE	Changed Information
Nov-11-2020 22:27:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 2: Reissued:Opened	DM : For AE# 3 and 4, Action taken with Study Treatment is recorded as "DRUG WITHDRAWN". However, Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. please update.
Nov-11-2020 16:43:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Query 2: Answered	Drug withdrawn due to AE
Nov-10-2020 20:08:48 (UTC-07:00) Mountain 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 20:08:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	issued in error
Nov-10-2020 19:19:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Opened	Only one primary Adverse Event should be chosen to have question 'Did the

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				adverse event cause the subject to be discontinued from the study? answered as YES if applicable. Please chose Primary Adverse Event.
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 23:29:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 2: Closed	Response satisfies query
Oct-09-2020 15:31:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 15:31:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Changed Information

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Oct-09-2020 15:31:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	Changed data per query
Oct-09-2020 15:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-08-2020 06:28:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	DM: 'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as 'ADVERSE EVENT'. Please review and update as appropriate. Thank you.
Oct-07-2020 06:09:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 2: Reissued:Opened	DM 1: More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes', please review and update as appropriate, thank you.
Oct-06-2020 13:05:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	Original value is correct

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Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'.
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-06-2020 13:04:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Initial Entry

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Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-12-2020 07:02:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Closed	Response satisfies query
Oct-09-2020 15:33:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	8lbs lost
Oct-08-2020 06:34:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Opened	Clin: Please clarify how much weight was lost during this period, no need to update term just please provide the information in response to this query
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: WEIGHT LOSS	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sep/14/2020 UNK:UNK	Initial Entry

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-18-2020 23:16:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Clo sed	Response satisfies query
Oct-17-2020 11:55:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Ans wered	Date is correct. CRC spoke with subject to verify end date on 10/6/2020.
Oct-14-2020 19:59:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW4978828;'End Date' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry : NO End Date Tim e: Oc t/4/ 20 20 U N K: U N K	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-06-2020 13:05:06 (UTC-07:00) Mountain	ACV0PFEINFP6000	Sahara Vega	Data Entry: 3	Initial Entry

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Subject Initials: ---

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Time (US & Canada)		(pfe.svega)	
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 17:44:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query
Nov-12-2020 09:57:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-12-2020 09:57:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NOT APPLICABLE	Changed Information
Nov-12-2020 05:19:17 (UTC-07:00) Mountain	ACV0PFEINFP6000	Cavin van Schalkwyk	Query 2: Reissued:Opened	DM : Both AE# 3 and 4, has a response to

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1012**Subject No:** 10121163**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1012) HOPE Research Institute**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

Time (US & Canada)		(pfe.vanscc01)		“Action taken with Study Treatment” as "DRUG WITHDRAWN". However, Only one primary Adverse Event should be chosen. please update.
Nov-11-2020 16:45:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Query 2: Answered	Action should be changed
Nov-10-2020 20:09:51 (UTC-07:00) Mountain 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 20:09:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	issued in error
Nov-10-2020 19:20:11 (UTC-07:00) Mountain 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.
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: DRUG WITHDRAWN	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Subject Initials: ---

Generated By: pfe.levissc

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Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 23:30:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 2: Closed	Response satisfies query
Oct-09-2020 15:32:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Oct-09-2020 15:32:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 15:32:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Changed Information
Oct-09-2020 15:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please

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Subject Initials: ---

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				review and update as appropriate.
Oct-08-2020 06:27:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	DM: 'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as 'ADVERSE EVENT'. Please review and update as appropriate. Thank you.
Oct-07-2020 06:10:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 2: Reissued:Opened	DM 1: More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes', please review and update as appropriate, thank you.
Oct-06-2020 13:06:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	Original value is correct
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'.
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION -

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				FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Oct-06-2020 13:05:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Initial Entry

Header Text: c4591001**Visit:** Disposition - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1012**Subject No:** 10121163**Generated By:** pfe.levisse**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1012) HOPE Research Institute**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Oct-10-2020 06:14:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe ks66)	Query 1: C losed	As per site response
Oct-09-2020 15:24:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: A nswered	Treatment was not unblinded. This is not applicable.
Oct-07-2020 00:16:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: O pened	DMW4905745;Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Oct-06-2020 13:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entr y: Not Applic able	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Oct-06-2020 13:00:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

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Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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I. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Oct-06-2020 11:46:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sep/24/2020	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121163

Generated By: pfe.levissc

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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I. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Oct-06-2020 13:00:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1012**Subject No:** 10121163**Generated By:** pfe.levisse**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1012) HOPE Research Institute**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Oct-14-2020 12:03:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-09-2020 15:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Changed Information
Oct-06-2020 11:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Sep-10-2020 18:45:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-10-2020 18:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-28-2020 16:31:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/17/2020	New Information
Oct-14-2020 12:03:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/24/2020	Initial Entry
Oct-09-2020 15:28:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/24/2020	Changed Information
Oct-06-2020 11:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/24/2020	Initial Entry
Sep-10-2020 18:45:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/9/2020	Initial Entry
Sep-10-2020 18:42:44 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/9/2020	Initial Entry

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Subject No: 10121163

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