

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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: 10121097

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 Aug/31/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[10121097]
2.	Birth Date:	(b) (6) 1948
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: 10121097

Generated By: pfe.levissc

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	Aug/31/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

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 _____
----	---	-------------------------

090177e196ae401d\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: 10121097

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	Aug/31/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

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:	[Basal Cell Carcinoma Nose]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoporosis]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left Knee Arthroplasty]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis Left Knee]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2017

090177e196ae401d\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: 10121097

Generated By: pfe.levisse

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sleep Apnea]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196ae401d\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: 10121097

Generated By: pfe.lewissc

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:	Aug/31/2020
2.	Weight:	[135.0]
3.	Unit:	LB
4.	Height:	[64.0]
5.	Unit:	in
6.	Body Mass Index:	[23.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae401d\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: 10121097

Generated By: pfe.levisse

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

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

Lab Urinalysis

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

Lab Result

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

090177e196ae401d\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: 10121097

Generated By: pfe.lewissc

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 :	Aug/31/2020
2.	Randomization Number:	[245283]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

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: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP43RH]
5.b	Sample ID	[BPL1P4]
5.c	Sample ID	[BPL1P5]

090177e196ae401d\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: 10121097

Generated By: pfe.lewissc

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: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP43RG]
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090177e196ae401d\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: 10121097

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:	Aug/31/2020 14:16
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

090177e196ae401d\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: 10121097

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: 10121097

Generated By: pfe.levissc

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/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP

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/21/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

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

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

Lab Urinalysis

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

Lab Result

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

090177e196ae401d\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: 10121097

Generated By: pfe.lewissc

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/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP4414]
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090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1012

Subject No: 10121097

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/21/2020 13:15
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

090177e196ae401d\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: 10121097

Generated By: pfe.levissc

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	Oct/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

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: Oct/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPL25D]
5.b	Sample ID	[BPL25F]
5.c	Sample ID	[BP9JCJ]

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Nov/11/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

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	Nov/11/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Nov/11/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/11/2020
2.	Date of First Symptom Started:	Nov/8/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Nov/12/2020

Symptoms

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

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Nov/11/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.a	Symptoms - Other Text:	[BODY ACHES]
-----	------------------------	--------------

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

5.c	Symptoms - Other Text:	[NASAL CONGESTION]
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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: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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.	Nov/11/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Nov/11/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Nov/11/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[Methodology: Real-Time RT-PCR; Quest lab]
9.	Trade Name Other, Specify:	[NALT Unknown]

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/11/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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?	YES Date of Collection: Nov/11/2020
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	[RW87460]
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090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB on Nov/11/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

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:	[Telehealth visit]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	Not Done _____ []	Comments
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090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Nov/11/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121097**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

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

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: 10121097

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

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Nov/11/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

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 **Form:** ILLNESS DETAILS
on Nov/11/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Illness Details

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

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: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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 **Form:** ILLNESS DETAILS - SEVERE
on Nov/11/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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: 10121097

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 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/11/2020

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae401d\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: 10121097

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 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/11/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

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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

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

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: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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 **Form:** VITAL SIGNS - COVID
on Nov/11/2020

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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 **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Nov/11/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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: 10121097

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 **Form:** OXYGENATION PARAMETERS
on Nov/11/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Nov/11/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

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Concomitant Medications

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

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

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: 10121097

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 **Form:** IMAGING
on Nov/11/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Dec/09/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Visit on Dec/09/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

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	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/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	[BRYKHX]
5.b	Sample ID	[BRYKHY]

090177e196ae401d\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: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: 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: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/20/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: 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: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

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: 10121097

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

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

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: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Left arm localized soreness at injection site	Sep/2/2020 UNK:UNK	NO End Date Time: Sep/3/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Vertigo	Feb/3/2021 00:00	NO End Date Time: Feb/5/2021 13:55	Repeating Pages
3.	ADVERSE EVENT	3	Chills	Feb/2/2021 21:30	NO End Date Time: Feb/3/2021 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Laceration on Head	Feb/3/2021 00:02	NO End Date Time: Feb/11/2021 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	Dizziness	Jan/24/2021 UNK:UNK	NO End Date Time: Jan/24/2021 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	Fever	Feb/3/2021 UNK:UNK	NO End Date Time: Feb/3/2021 UNK:UNK	Repeating Pages

090177e196ae401d\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: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

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

090177e196ae401d\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: 10121097

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Vertigo]
4.	Start Date Time:	Feb/3/2021 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/5/2021 13:55
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae401d\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: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021112566]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chills]
4.	Start Date Time:	Feb/2/2021 21:30
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/3/2021 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

090177e196ae401d\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: 10121097

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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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)	[Laceration on Head]
4.	Start Date Time:	Feb/3/2021 00:02
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/11/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Vertigo]

090177e196ae401d\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: 10121097

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Dizziness]
4.	Start Date Time:	Jan/24/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/24/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]

090177e196ae401d\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: 10121097

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

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

090177e196ae401d\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: 10121097

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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

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: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

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

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Medication Error

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

090177e196ae401d\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: 10121097

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.	1	VACCINATIONS	NO	Seasonal Influenza Vaccine	Oct/16/2020	Repeating Pages

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Seasonal Influenza Vaccine]
5.	Date:	Oct/16/2020

090177e196ae401d\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: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

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

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Concomitant Medications

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

090177e196ae401d\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: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

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

090177e196ae401d\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: 10121097

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001	
Visit: Logs - Unscheduled	Form: TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	Form Status: Not Started
Site No: 1012	Site Name: (1012) HOPE Research Institute
Subject No: 10121097	Subject Initials: ---
Generated By: pfe.levisse	Generated Time (GMT): 29-Mar-2021 04:21

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

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:	

090177e196ae401d\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: 10121097

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?	

090177e196ae401d\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: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/13/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/13/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: DATE OF VISIT

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](#)

Date of Visit

1.	Date of Visit	Jan/13/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: INFORMED CONSENT - FURTHER VACCINATION

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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/13/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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 - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/13/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001**Visit:** V101_VAX3**Form Version:** 14-Jan-2021 02:21**Site No:** 1012**Subject No:** 10121097**Generated By:** pfe.levissc**Form:** LAB URINALYSIS - PREGNANCY TEST**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](#)

Lab Urinalysis

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

Lab Result

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/13/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9JJF]
5.b	Sample ID	[BRYKKN]
5.c	Sample ID	[BRYKKM]

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/13/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9JJD]
-----	-----------	----------

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: VACCINATION

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

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/13/2021 15:48
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: DATE OF VISIT

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](#)

Date of Visit

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8XCL]
-----	-----------	----------

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: VACCINATION

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

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/2/2021 11:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: DATE OF VISIT

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](#)

Date of Visit

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

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

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](#)

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

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	FOLLOW-UP
2.	Subject Status Date	Oct/20/2020

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: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

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: 10121097

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: 10121097

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-01-2020 13:29:25 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Not Applicable
			Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
1	Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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	Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

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Subject Initials: ---

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

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Item	Date	User	Comment
3	Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

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Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
4	Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

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Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
5	Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential
			Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential
			Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
Form	Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential _____ Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
1	Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
2	Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential Not Applicable

Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

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

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Item	Date	User	Comment
3	Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential Not Applicable

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Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
4	Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

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Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Item	Date	User	Comment
5	Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

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Subject No: 10121097

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Site Name: (1012) HOPE Research Institute

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

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Item	Date	User	Comment
6.a	Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1012

Subject No: 10121097

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Item	Date	User	Comment
6.a	Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential
			Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

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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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Item	Date	User	Comment
6.a	Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject is not of childbearing potential
			Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5.a	Nov-12-2020 09:12:14 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Not Done

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Jan-14-2021 17:36:19 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Met all criteria <hr/> Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
Form	Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Hysterectomy <hr/> Not Applicable

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
1	Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Hysterectomy
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
2	Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Hysterectomy
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
3	Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Hysterectomy
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
4	Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Hysterectomy
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
5	Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Hysterectomy
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Hysterectomy
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Hysterectomy
			Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Hysterectomy
			Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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	Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	SURGICALLY STERILE <hr/> Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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	Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	SURGICALLY STERILE Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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	Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	SURGICALLY STERILE Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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	Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	SURGICALLY STERILE <hr/> Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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
4	Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	SURGICALLY STERILE Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
5	Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	SURGICALLY STERILE Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	SURGICALLY STERILE
			Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	SURGICALLY STERILE Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	SURGICALLY STERILE
			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: 10121097

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
Sahara Vega	N/A	Jan-25-2021 16:36:36 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Matthew Doust	Approved	Jan-22-2021 08:46:51 (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.

Sahara Vega	N/A	Jan-14-2021 17:35:20 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Matthew Doust	Approved	Dec-11-2020 10:57:26 (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.

090177e196ae401d\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:** 10121097**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21

Sahara Vega	N/A	Dec-09-2020 14:59:27 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Matthew Doust	Approved	Nov-16-2020 17:44:38 (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.

Sahara Vega	N/A	Nov-16-2020 13:33:13 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Matthew Doust	Approved	Nov-16-2020 09:05:46 (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.

Sahara Vega	N/A	Nov-12-2020 16:40:23 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

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: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

Matthew Doust	Approved	Nov-12-2020 13:38:12 (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.

Sahara Vega	N/A	Nov-12-2020 09:09:10 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Matthew Doust	Approved	Oct-26-2020 16:10:40 (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.

090177e196ae401d\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: 10121097

Generated By: pfe.lewissc

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-01-2020 13:28:17 (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-01-2020 13:28:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

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-01-2020 13:28:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: OBTAINED Date Written Consent Obtained Aug/31/2020	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

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-01-2020 13:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10121097	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-01-2020 13:28:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1948	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-01-2020 13:28:48 (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-01-2020 13:28:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:28:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: WHITE	Initial Entry

090177e196ae401d\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: 10121097

Generated By: pfe.levissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 13:29:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

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-01-2020 13:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Aug/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-01-2020 13:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-14-2020 23:05:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricardo DABreau (pfe.dabrer02)	Query 1: Closed	Response satisfies query
Sep-06-2020 10:58:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Will confirm start date of insomnia at next visit.
Sep-04-2020 10:45:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricardo DABreau (pfe.dabrer02)	Query 1: Opened	Concomitant medication log list Ambien with a start date of 2010 for insomnia. Please confirm medical history.
Sep-01-2020 13:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: COMPLETED	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Sep-04-2020 10:46:12 (UTC-07:00) Mountain	ACV0PFEINFP6000	Ricardo DABreau	Query 1: Closed	Response satisfies query

090177e196ae401d\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: 10121097

Generated By: pfe.levisse

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

Time (US & Canada)		(pfe.dabrer02)		
Sep-04-2020 10:43:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricardo DAbreau (pfe.dabrer02)	Query 1: Opened	Source list documented hysterectomy 1990. Please verify.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

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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1.a

Date	Location	User	Value	Reason
Sep-03-2020 17:32:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Basal Cell Carcinoma Nose Start Date: UNK/UNK/2018 Ongoing: NO End Date: UNK/UNK/2018	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 17:32:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 17:32:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Basal Cell Carcinoma Nose	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 17:32:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: UNK/UNK/2018	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
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090177e196ae401d\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: 10121097

Generated By: pfe.levisse

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-03-2020 17:32:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry
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1.b

Date	Location	User	Value	Reason
Sep-03-2020 17:32:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History Term: Osteoporosis Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

090177e196ae401d\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: 10121097

Generated By: pfe.levisse

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-03-2020 17:32:56 (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-03-2020 17:32:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Osteoporosis	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 17:32:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: UNK/UNK/2016	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 17:32:56 (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-03-2020 17:34:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 3 ber: Medical Histor Left Knee Arthr y Term: oplasty Start Date: UNK/UNK/201 7	Initial Entry

090177e196ae401d\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: 10121097

Generated By: pfe.levisse

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:	NO	
				End Date:	
				UNK/UNK/2017	

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 17:34:09 (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-03-2020 17:34:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Left Knee Arthroplasty	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 17:34:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: UNK/UNK/2017	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 17:34:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-03-2020 17:35:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4	Initial Entry

090177e196ae401d\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: 10121097

Generated By: pfe.levisse

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

			Medical History Term: Osteoarthritis Left Knee	
			Start Date: UNK/UNK/2014	
			Ongoing: NO	
			End Date:	
			UNK/UNK/2017	

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1012**Subject No:** 10121097**Generated By:** pfe.levisse**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.d Line/MH Number:**

Date	Location	User	Value	Reason
Sep-03-2020 17:35:06 (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
Oct-01-2020 06:50:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Charlene Kimmel (pfe.kimtec)	Query 1: Closed	Response satisfies query
Sep-28-2020 12:19:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Query 1: Answered	Insomnia and sleep apnea have been added to medical history
Sep-28-2020 06:41:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Charlene Kimmel (pfe.kimtec)	Query 1: Opened	confirm if insomnia and sleep apnea should be added
Sep-03-2020 17:35:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Osteoarthritis Left Knee	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 17:35:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: UNK/UNK/2014	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 17:35:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

I.e

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-28-2020 12:18:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 5 : Medical History T Insomnia erm: Start Date: UNK/UNK/2 010 Ongoing: YES	Initial Entry

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 12:18:01 (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-28-2020 12:18:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Insomnia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 12:18:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: UNK/UNK/2010	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 12:18:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
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090177e196ae401d\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: 10121097

Generated By: pfe.levisse

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-28-2020 12:18:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 6 : Medical History T Sleep Apnea erm: Start Date: UNK/UNK/2 010 Ongoing: YES	Initial Entry
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1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-28-2020 12:18:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 12:18:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sleep Apnea	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-28-2020 12:18:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: UNK/UNK/2010	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Sep-28-2020 12:18:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES	Initial Entry

090177e196ae401d\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: 10121097

Generated By: pfe.lewissc

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-01-2020 13:30:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Aug/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-01-2020 13:30:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 135.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 13:30:58 (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-01-2020 13:30:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 64.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 13:30:58 (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-01-2020 13:30:58 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23.2	Initial Entry

090177e196ae401d\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: 10121097

Generated By: pfe.levisse

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

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Sep-01-2020 13:30:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Record Identifier: 1 : Temperature: 97.2 Temperature Unit F : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 13:30:58 (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-01-2020 13:30:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 97.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 13:30:58 (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-01-2020 13:30:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae401d\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: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae401d\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: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sponsor-Defined Id Not Applic entifier: able Test:: Not Applic able Result:: Not Applic able Not Done:: Not Applic able	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-01-2020 13:31:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

090177e196ae401d\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: 10121097

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-01-2020 13:33:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Aug/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-01-2020 13:33:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 245283	Initial Entry

090177e196ae401d\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: 10121097

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-01-2020 13:33:39 (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-01-2020 13:33:39 (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-02-2020 14:12:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-02-2020 00:53:34 (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-01-2020 13:33:39 (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-01-2020 13:33:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

090177e196ae401d\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: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Sep-02-2020 14:12:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Sample ID: BP43RH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 14:12:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: BP43RH	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-02-2020 14:13:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Sample ID: BPL1P4	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 14:13:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: BPL1P4	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-02-2020 14:13:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Sample ID: BPL1P5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 14:13:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: BPL1P5	Initial Entry

090177e196ae401d\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: 10121097

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-01-2020 13:34:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 13:34:02 (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-02-2020 14:12:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-02-2020 00:58:44 (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-01-2020 13:34:02 (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-01-2020 13:34:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

090177e196ae401d\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: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Sep-02-2020 14:12:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Sample ID: BP43RG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 14:12:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: BP43RG	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

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-01-2020 13:34:35 (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-01-2020 13:34:35 (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-01-2020 13:34:35 (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-01-2020 13:34:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Aug/31/2020 14:16	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 13:34:35 (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-01-2020 13:34:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke	Data Entry: LEFT	Initial Entry

090177e196ae401d\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: 10121097

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

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

Date	Location	User	Value	Reason
Sep-01-2020 13:34:35 (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-01-2020 13:34:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 13:34:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES	Initial Entry

090177e196ae401d\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: 10121097

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-01-2020 13:34:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-21-2020 15:56:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sep/21/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - 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-21-2020 15:57:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sep/21/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 15:57:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Record Identifier: 1 : Temperature: 97.6 Temperature Unit F : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 15:57:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-21-2020 15:57:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 97.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-21-2020 15:57:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: F	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - 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

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-21-2020 15:57:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sponsor-Defined Id entifier: Not Applic able Test:: Not Applic able Result:: Not Applic able Not Done:: Not Applic able	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-21-2020 15:57:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Not Applicable	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

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-21-2020 15:58:04 (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-21-2020 15:58:04 (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-29-2020 16:01:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 01:49:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 15:58:04 (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-21-2020 15:58:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Sep-29-2020 16:01:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Shana Harshell (pfe.sharshell)	Data Entry: Sample ID: BP4414	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 16:01:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Shana Harshell (pfe.sharshell)	Data Entry: BP4414	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

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-21-2020 15:58:49 (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-21-2020 15:58:49 (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-21-2020 15:58:49 (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-21-2020 15:58:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sep/21/2020 13:15	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 15:58:49 (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-21-2020 15:58:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke	Data Entry: LEFT	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Sep-21-2020 15:58:49 (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-21-2020 15:58:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 15:58:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES	Initial Entry

090177e196ae401d\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: 10121097

Generated By: pfe.levissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Oct-20-2020 15:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Oct/20/2020	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-20-2020 15:10:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-20-2020 15:10:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-21-2020 11:33:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-21-2020 04:34:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-20-2020 15:10:30 (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.
Oct-20-2020 15:10:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: YES Date of Collection: Oct/20/2020	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Oct-21-2020 11:33:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: BPL25D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 11:33:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BPL25D	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-21-2020 11:34:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: BPL25F	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 11:34:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BPL25F	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 11:35:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: BP9JCJ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 11:35:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BP9JCJ	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/11/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121097**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-16-2020 14:09:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 3: Closed	Response satisfies query
Nov-16-2020 13:33:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 3: Answered	Changed data per query
Nov-13-2020 12:17:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 3: Opened	Per CCGs the COVID Test is a required form within this visit. Please complete the data as required in CCG section 8.31. If the test was not done please add a FORM LEVEL comment of NOT DONE else clarify.
Nov-12-2020 09:11:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-12-2020 09:09:09 (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-12-2020 09:09:09 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/11/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)				of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-12-2020 09:09:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Nov/11/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-12-2020 09:09:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Nov/11/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Nov/8/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 10:39:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Closed	Response satisfies query
Jan-20-2021 12:58:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-20-2021 12:58:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO Date of Last Symptom Resolved: Nov/12/2020	Transcription Error
Dec-29-2020 11:56:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Opened	per the Convalescent visit source symptoms resolved on 12 Nov 2020. Please revisit and update.
Dec-09-2020 14:59:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO Date of Last Symptom Resol	New Information

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

			ved: Nov/11/2020	
Nov-12-2020 09:10:28 (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-12-2020 09:10:28 (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-12-2020 09:10:28 (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-12-2020 09:10:28 (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-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121097**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**4.b Symptoms:**

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (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-12-2020 09:10:28 (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-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptom: NEW OR INCREASE D SHORTNESS OF B REATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NEW OR INCREASED SHORTN ESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121097**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

Nov-13-2020 15:47:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Transcription Error
Nov-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (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-14-2020 09:31:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kimberly Forbus (pfe.forbuk)	Query 1: Closed	Response satisfies query
Nov-13-2020 15:47:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-13-2020 15:47:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO	Transcription Error
Nov-13-2020 13:55:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Opened	per source denies chills, please revisit and update.
Nov-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptom NEW OR INCREAS	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Nov/11/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121097**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

s:	ED MUSCLE PAIN
Symptom	NO
Present:	

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NEW OR INCREASED MUSCL E PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (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-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms NEW LOSS OF TAS : TE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NEW LOSS OF TASTE OR SME LL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (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 Nov/11/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

4.g

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (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-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121097**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**4.h Symptoms:**

Date	Location	User	Value	Reason
Nov-12-2020 09:10:28 (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-12-2020 09:10:28 (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-12-2020 09:10:28 (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-12-2020 09:10:28 (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-12-2020 09:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-12-2020 09:10:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms - Other: BODY ACHE S	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-12-2020 09:10:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BODY ACHES	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-12-2020 09:10:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms - Other: FATIGUE	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-12-2020 09:10:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: FATIGUE	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-12-2020 16:40:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms - Other: NASAL CONGESTION	Changed Information
Nov-12-2020 09:11:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptoms - Other: CONGESTION	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-13-2020 00:43:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Nov-12-2020 16:40:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-12-2020 16:40:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NASAL CONGESTION	Changed Information
Nov-12-2020 11:43:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify CONGESTION as follows...The term appears incomplete. Are you reporting NASAL CONGESTION? SINUS CONGESTION? HEPATIC CONGESTION? Other? If so, edit as such. If there is no further information, update the current term to CONGESTION NFI. Otherwise please note the term remains uncoded in the database. Thank you.

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-12-2020 09:11:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: CONGESTI ON	Initial Entry
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090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Nov/11/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Nov-16-2020 13:33:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/11/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Nov/11/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:13 (UTC-07:00) Mountain	ACV0PFEINFP6000	Sahara Vega	Data Entry: OTHER	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/11/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)

(pfe.svega)

7. Test Result:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NEGATIVE	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Methodology: Real-Time RT-PCR; Quest lab	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NALT Unknown	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Nov/11/2020**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:** 10121097**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-12-2020 09:11:18 (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-12-2020 09:11:18 (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-12-2020 09:12:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-12-2020 09:11:18 (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.
Nov-12-2020 09:11:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES Date of Collection: Nov/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-12-2020 09:12:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: RW87460	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 09:12:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: RW87460	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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1. Data Origin

Date	Location	User	Value	Reason
Nov-12-2020 09:12:05 (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-12-2020 09:12:05 (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-12-2020 09:12:05 (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-12-2020 09:12:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Telehealth visit	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-12-2020 09:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: Not Done	Initial Entry
Nov-12-2020 09:11:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID:	Transcription Error

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-12-2020 09:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: RW87460	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 09:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Done	Initial Entry
Nov-12-2020 09:11:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-12-2020 09:11:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry:	Transcription Error
Nov-12-2020 09:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Nov-12-2020 09:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: RW87460	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/11/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

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
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: SPECIA LIST Occurrence of Visits o r Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practition EMERGEN er: CY ROOM Occurrence of Visi NO ts or Contacts:	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/11/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121097**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/11/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

I.d

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner URGENT : CARE Occurrence of Visits NO or Contacts:	Initial Entry

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/11/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121097**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 09:13:30	ACV0PFEINFP6000	Sahara	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/11/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-07:00) Mountain Time (US & Canada)		Vega (pfe.svega)	NO	
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Nov/11/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-12-2020 09:13:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 09:13:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-12-2020 09:13:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: 1	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/09/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-09-2020 14:59:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Dec/9/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-09-2020 14:59:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: COVID_A1	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/09/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Dec-09-2020 14:59:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-09-2020 14:59:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 13:05:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-11-2020 10:41:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-09-2020 14:59:58 (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.
Dec-09-2020 14:59:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES Date of Collection: Dec/9/2020	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/09/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Jan-20-2021 13:05:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Sample ID: BRYKHX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 13:05:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: BRYKHX	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-20-2021 13:06:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Sample ID: BRYKHY	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 13:06:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: BRYKHY	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-20-2020 15:10:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Oct/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-20-2020 15:10:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-20-2020 15:10:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: COMPLETED	Initial Entry

090177e196ae401d\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: 10121097

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-05-2021 14:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-11-2021 11:49:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Form Created	

Header Text: c4591001

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Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-11-2021 11:50:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Form Created	

Header Text: c4591001

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Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

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Form Status: Data Complete, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Sep-23-2020 16:39:23 (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
Sep-23-2020 16:39:23 (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
Feb-25-2021 13:17:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Feb-25-2021 13:16:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-05-2021 14:15:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 2: Answered	Added
Feb-05-2021 14:14:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	Added
Feb-05-2021 09:28:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL On review of the SAE report for VERTIGO, an event of Laceration (7 stitches) has been mentioned, yet it does not appear in the CRF. Please review for safety

090177e196ae401d\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:** 10121097**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - 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

				and update AE log CRF accordingly.
Feb-05-2021 09:27:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical SAE of Vertigo reported (#2021112566); please enter event on the AE CRF
Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Left arm localized soreness at injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Sep/2/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO End Date Time: Sep/3/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

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Subject Initials: ---

Generated By: pfe.levisse

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Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO	Initial Entry
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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Generated By: pfe.levisse

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Form Status: Data Complete, Frozen, Verified

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Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: RECOVERED/RESOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-23-2020 16:39:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Verified

Site No: 1012

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Subject Initials: ---

Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Feb-05-2021 14:08:29 (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
Feb-05-2021 14:08:29 (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
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Vertigo	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-05-2021 17:47:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Mar-02-2021 09:16:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	These dates have been changed on the SAE; corrected report was sent in last week.
Mar-02-2021 06:14:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Opened	Clinical In the recent SAE update, the date for the CXR and Head CT entered in the Test section is 02Feb21, which is the day

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1012**Subject No:** 10121097**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - 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

				BEFORE the SAE event occurred. Please update this date as soon as possible in a SAE safety update. Thank you.
Mar-01-2021 14:32:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Candidate	Clinical In the recent SAE update, the date for the CXR and Head CT entered in the Test section is 02Feb21, which is the day BEFORE the SAE event occurred. Please update this date as soon as possible in a SAE safety update. Thank you.
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Feb/3/2021 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 16:20:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Mar-09-2021 13:39:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	THERE IS ABSOLUTELY AN END DATE ON PAGE 2 AT THE BOTTOM (SECTION 17) AND IN THE NARRATIVE. IS THERE ANOTHER THAT I NEED TO ADD THE STOP DATE?

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Mar-08-2021 23:36:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical - most recent SAE update (04Mar21) does not have an End date - please submit to the SAE event section at STOP date
Mar-08-2021 09:18:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	Updated SAE was submitted last week on 04Mar2021
Mar-05-2021 17:49:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - End date is 05Feb21; however, SAE report has no End date. Please submit a SAE update reporting End date and resolved status
Mar-04-2021 13:49:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO End Date Time: Feb/5/2021 13:55	New Information
Mar-02-2021 09:37:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe.mmikulak)	Data Entry: NO End Date Time: Feb/3/2021 13:55	New Information
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Feb-25-2021 13:23:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Query closed; will follow for requested COVID test information.
Feb-24-2021 10:21:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 2: Answered	This was submitted today.
Feb-22-2021 09:12:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical – Thank you. If NO hospital COVID test was performed is known, please submit this information on a follow-up SAE form, as pertinent information for this trial.
Feb-17-2021 10:53:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant dis	Changed Information

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			ability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	
Feb-17-2021 10:53:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 2: Answered	No COVID testing was performed
Feb-08-2021 16:55:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021112566] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Feb-08-2021 07:49:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Vertigo: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: YES Is this serious event associate	Initial Entry

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			<p>d with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
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8. Is this adverse event the result of a study Medication Error?

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

Date	Location	User	Value	Reason
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-17-2021 10:46:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NOT RELATED If Not Related to study treatm	New Information

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			ent(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown	
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 05:17:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Closed	Response satisfies query
Mar-08-2021 00:09:27	ACV0PFEINFP6000	Ricell Ann Piojo	Query 3: Reissued: Candidate	Pending SDB update

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(UTC-07:00) Mountain Time (US & Canada)		(pfe.QUITOR)		
Mar-04-2021 13:58:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 3: Answered	Updated SAE report submitted.
Mar-03-2021 23:56:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 3: Opened	SAE RECON:AER#2021112566 ,outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/Resolving in Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Mar-02-2021 09:37:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-02-2021 09:37:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe.mmikulak)	Data Entry: RECOVERED/RE SOLVED	New Information
Mar-02-2021 09:37:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Vertigo: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-19-2021 01:53:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Closed	Response satisfies query
Feb-18-2021 01:41:08 (UTC-07:00) Mountain Time	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Reissued: Candidate	Pending SDB update

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(US & Canada)				
Feb-17-2021 10:46:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	SAE report has been updated.
Feb-09-2021 20:49:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2021112566,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: RECOVERING/RE SOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 14:08:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-08-2021 07:49:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Data Entry: 2021112566	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Feb-05-2021 14:10:01 (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
Feb-05-2021 14:10:01 (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
Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Chills	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Feb/2/2021 21:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO End Date Time: Feb/3/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Generated By: pfe.levisse

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Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 14:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

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Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Feb-05-2021 14:14:15 (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
Feb-05-2021 14:14:15 (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
Feb-05-2021 14:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Laceration on Head	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-05-2021 14:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Feb/3/2021 00:02	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-11-2021 11:48:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO End Date Time: Feb/11/2021 UNK:UNK	New Information
Feb-05-2021 14:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: YES	Initial Entry

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-05-2021 14:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-05-2021 14:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-05-2021 14:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-09-2021 23:56:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Closed	Query closed data has been updated
Feb-09-2021 15:39:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-09-2021 15:39:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NOT RELATED If Not Related to study treatm ent(s), this event is due to:	New Information

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

			OTHER <i>If Other, specify:</i> Vertigo	
Feb-08-2021 04:12:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "Is this event related to study treatment" is missing. Kindly review and update.

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-05-2021 14:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-05-2021 14:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-05-2021 14:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 11:48:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-11-2021 11:48:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: RECOVERED/RESOLVED	New Information

090177e196ae401d\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: 10121097

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Feb-11-2021 11:48:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Laceration on Head: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-05-2021 14:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: RECOVERING/RESOLVIN G	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 14:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Feb-11-2021 11:49:28 (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
Feb-11-2021 11:49:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-24-2021 23:07:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Closed	verified
Feb-24-2021 17:57:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Tonye Sylvanus (pfe.tsylvanus)	Query 1: Answered	Source uploaded
Feb-24-2021 13:15:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Opened	unable to verify, source unavailable
Feb-11-2021 11:49:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Dizziness	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-11-2021 11:49:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Jan/24/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Feb-11-2021 11:49:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO End Date Time: Jan/24/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-11-2021 11:49:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-11-2021 11:49:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-11-2021 12:54:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-11-2021 12:54:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

			OTHER <i>If Other, specify:</i> Unknown	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-11-2021 11:49:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-11-2021 11:49:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-11-2021 11:49:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 11:49:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 11:49:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

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Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Feb-11-2021 11:50:09 (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
Feb-11-2021 11:50:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-24-2021 23:10:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 2: Closed	verified
Feb-24-2021 17:58:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Tonye Sylvanus (pfe.tsylvanus)	Query 2: Answered	Source uploaded
Feb-24-2021 13:17:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 2: Opened	unable to verify, source unavailable
Feb-18-2021 12:23:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Closed	Response satisfies query
Feb-17-2021 10:51:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	Due to vaccine reactogenicity
Feb-14-2021 18:06:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: Per Prot Sect 8.1., please review if FEVER a COVID-19 listed symptoms, start

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1012**Subject No:** 10121097**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - 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

				date 2d post Vax 4, is due to vaccine reactogenicity or is more related to COVID-19 (should have triggered a potential COVID Illness Visit)
Feb-11-2021 11:50:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Fever	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-17-2021 10:48:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Feb/3/2021 UNK:UNK	Changed Information
Feb-11-2021 11:50:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Feb/4/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-17-2021 21:44:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Closed	Response satisfies query
Feb-17-2021 10:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-17-2021 10:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO End Date Time: Feb/3/2021 UNK:UNK	New Information
Feb-16-2021 23:21:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Opened	This event is not ongoing, hence please update end date.

Header Text: c4591001

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Generated By: pfe.levisse

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Form Status: Data Complete, Frozen, Verified

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Feb-11-2021 11:50:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-11-2021 11:50:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-11-2021 11:50:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-17-2021 10:50:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-17-2021 10:50:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: RELATED	Changed Information
Feb-11-2021 12:54:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NOT RELATED If Not Related to study treatm ent(s), this event is due to:	Initial Entry

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Header Text: c4591001

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Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - 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

			OTHER <i>If Other, specify:</i> Unknown	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-11-2021 11:50:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-17-2021 10:50:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-17-2021 10:50:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 11:50:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 11:50:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: NO	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Oct-20-2020 15:11:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-20-2020 15:11:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-20-2020 15:11:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-20-2020 15:11:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-20-2020 15:11:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Seasonal Influenza Vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-20-2020 15:11:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Data Entry: Oct/16/2020	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-14-2021 17:35:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Jan/13/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - 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

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

Date	Location	User	Value	Reason
Jan-20-2021 12:58:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-14-2021 22:05:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-14-2021 17:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-14-2021 17:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible per other protocol al lowance(s) and confirmed to have received only placebo a t Vaccination 1/2	Initial Entry

090177e196ae401d\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: 10121097

Generated By: pfe.levissc

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-20-2021 12:58:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Jan/13/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-20-2021 12:58:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: DATE OF VISIT - 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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-14-2021 17:35:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Jan/13/2021	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: INFORMED CONSENT - FURTHER VACCINATION - 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

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-14-2021 17:36:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: OBTAINED Date Written Consent Obtained Jan/13/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION
- eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-14-2021 17:36:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Jan/13/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-14-2021 17:36:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-14-2021 17:36:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: COMPLETED	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sponsor-Defined Identifier: Test:: Result:: Not Done::	Initial Entry Not Applicable Not Applicable Not Applicable Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-14-2021 17:37:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

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
Jan-14-2021 17:37:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-14-2021 17:37:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-26-2021 03:14:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Malerato Molo (pfe.moloim)	Query 1: Closed	Response satisfies query
Jan-25-2021 16:37:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Jan-20-2021 22:53:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Reissued:Opened	DM: If sample collected yes then barcode details needs to be reported. Kindly consider updating data as appropriate or else clarify. Thank you.
Jan-20-2021 13:00:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	UNABLE TO ADD BARCODES
Jan-14-2021 21:18:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

				entered. Please review and correct as appropriate.
Jan-14-2021 17:37:33 (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.
Jan-14-2021 17:37:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES Date of Collection: Jan/13/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 16:37:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: BP9JJF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 16:37:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BP9JJF	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-25-2021 16:37:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: BRYKKN	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 16:37:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BRYKKN	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-25-2021 16:37:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: BRYKKM	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 16:37:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BRYKKM	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

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
Jan-14-2021 17:37:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-14-2021 17:37:44 (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
Jan-26-2021 02:57:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Jan-25-2021 16:36:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Jan-20-2021 21:27:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Reissued:Opened	DM : Form is unfrozen now. 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-20-2021 13:00:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	UNABLE TO ADD BARCODE
Jan-14-2021 21:18:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

				review and correct as appropriate.
Jan-14-2021 17:37:44 (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.
Jan-14-2021 17:37:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES Date of Collection: Jan/13/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 16:36:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: BP9JJD	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 16:36:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BP9JJD	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1012

Subject No: 10121097

Generated By: pfe.lewissc

Form: VACCINATION - 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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-14-2021 17:38:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-14-2021 17:38:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-14-2021 17:38:08 (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
Jan-14-2021 17:38:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Jan/13/2021 15:48	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-14-2021 17:38:08 (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
Jan-14-2021 17:38:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega	Data Entry: LEFT	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Jan-14-2021 17:38:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-14-2021 17:38:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-14-2021 17:38:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-14-2021 17:38:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-14-2021 17:38:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: DATE OF VISIT - 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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-03-2021 09:43:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Feb/2/2021	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

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
Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sponsor-Defined Identifier: Test: Result: Not Done:	Initial Entry Not Applicable Not Applicable Not Applicable Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 09:44:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Not Applicable	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-03-2021 09:44:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-03-2021 09:44:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-03-2021 12:10:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe ratnaa05)	Query 2: Closed	issued in error
Mar-03-2021 12:05:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe ratnaa05)	Query 2: Opened	unable to verify, please upload the source supporting the data
Feb-08-2021 17:48:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 02:27:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-03-2021 09:44:26 (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

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

				as appropriate.
Feb-03-2021 09:44:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES Date of Collection: Feb/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-08-2021 17:48:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Sample ID: BR8XCL	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-08-2021 17:48:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: BR8XCL	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: VACCINATION - 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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-03-2021 09:44:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-03-2021 09:44:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-03-2021 09:44:55 (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
Mar-03-2021 12:11:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Closed	issued in error
Mar-03-2021 12:04:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Opened	unable to verify data entered, please revisit and upload
Feb-03-2021 09:44:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Feb/2/2021 11:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
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090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levisse

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

Feb-03-2021 09:44:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
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6. Body Side:

Date	Location	User	Value	Reason
Feb-03-2021 09:44:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-03-2021 09:44:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-03-2021 09:44:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-03-2021 09:44:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-03-2021 09:44:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1012

Subject No: 10121097

Generated By: pfe.levisse

Form: VACCINATION - 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

Feb-03-2021 09:44:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: DATE OF VISIT - 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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 09:48:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	Data Entry: Mar/2/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

Form: CONTACT OUTCOME - 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

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1. Contact Type:

Date	Location	User	Value	Reason
Mar-02-2021 09:48:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-02-2021 09:48:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	Data Entry: YES Date of Contact: Mar/2/2021	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** FURTHER_VACCINATION_EOT -
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121097**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-03-2021 04:32:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ashwini Devi Subhash (pfe.subhaa)	Query 1: Clo sed	incorrect
Mar-03-2021 00:44:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7580661;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Mar-02-2021 09:48:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe.mmikulak)	Data Entry : Mar/2 /2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-02-2021 09:48:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-02-2021 09:48:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

Generated By: pfe.levissc

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-20-2020 15:10:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-01-2020 13:33:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-01-2020 13:30:12 (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
Feb-08-2021 07:49:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Closed	Response satisfies query
Feb-05-2021 13:21:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Opened	SAE RECON:AER#2021112566 vertigo (onset date 03-FEB-2021) was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-20-2020 15:10:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/20/2020	Initial Entry
Sep-01-2020 13:33:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae401d\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121097

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

Sep-01-2020 13:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121097

Subject Initials: ---

Generated By: pfe.levissc

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-26-2020 15:58:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: Click Here to Enable	Initial Entry