

**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 10121112

**Generated By:** pfe.lewissc

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1012) HOPE Research Institute

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/2/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1012

**Subject No:** 10121112

**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	[10121112]
2.	Birth Date:	(b) (6)/1940
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1012

**Subject No:** 10121112

**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/2/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1012

**Subject No:** 10121112

**Generated By:** pfe.levisse

**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
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**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable
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**Header Text:** c4591001

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

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

**Site No:** 1012

**Subject No:** 10121112

**Generated By:** pfe.lewissc

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1012) HOPE Research Institute

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Sep/2/2020
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: 10121112

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY

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](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[PROSTATE CANCER]
	Start Date:	Dec/UNK/1987
	Ongoing:	NO End Date: Dec/UNK/1987
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[PROSTATECTOMY]
	Start Date:	Dec/UNK/1987
	Ongoing:	NO End Date: UNK/UNK/1987
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SQUAMOUS CELL CARCINOMA ON FACE]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERLIPIDEMIA]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES

090177e196ae401e\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:** 10121112

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, 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:	[VASECTOMY]
	Start Date:	UNK/UNK/1977
	Ongoing:	NO End Date: UNK/UNK/1977
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SEASONAL ALLERGIES]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[LEFT KNEE REPLACEMENT]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GENERALIZED OSTEOARTHRITIS]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

090177e196ae401e\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:** 10121112

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1012) HOPE Research Institute

**Subject Initials:** ---

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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Heart Arrhythmia]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Loop Recorder Implant]
	Start Date:	Oct/UNK/2019
	Ongoing:	NO End Date: Oct/UNK/2019
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Mitral Valve Prolapse]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bilateral hearing loss]
	Start Date:	UNK/UNK/1964
	Ongoing:	YES

090177e196ae401e\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:** 10121112

**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:	Sep/2/2020
2.	Weight:	[170.0]
3.	Unit:	LB
4.	Height:	[69.0]
5.	Unit:	in
6.	Body Mass Index:	[25.1]

**Vital Signs Details**

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

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**Header Text:** c4591001

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

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

**Site No:** 1012

**Subject No:** 10121112

**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 :	Sep/2/2020
2.	Randomization Number:	[249283]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1012

**Subject No:** 10121112

**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: Sep/2/2020
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	[BP43SP]
5.b	Sample ID	[BPL1R4]
5.c	Sample ID	[BPL1R5]

090177e196ae401e\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:** 10121112

**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/2/2020
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	[BP43SN]
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090177e196ae401e\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:** 10121112

**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/2/2020 11:01
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

090177e196ae401e\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:** 10121112

**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:** 10121112

**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:** 10121112

**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:	[96.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1012

**Subject No:** 10121112

**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	[BP4413]
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090177e196ae401e\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:** 10121112

**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 13:13
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae401e\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:** 10121112

**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:** 10121112

**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	[BPL25G]
5.b	Sample ID	[BPL25H]
5.c	Sample ID	[BP9JCK]

090177e196ae401e\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 Dec/03/2020

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

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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/3/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Dec/03/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121112

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:	Dec/3/2020
2.	Date of First Symptom Started:	Dec/2/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/2/2020

**Symptoms**

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

090177e196ae401e\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 Dec/03/2020

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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.	Symptoms - Other Text:	[ ]
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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:** 10121112

**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.	Dec/2/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Dec/03/2020

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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:	Dec/2/2020
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:	[COVID-19 Swab/Non-Swab (SQ); Sonora Quest Laboratories]
9.	Trade Name Other, Specify:	[NALT Unknown]

090177e196ae401e\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 Dec/03/2020

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

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Dec/2/2020
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	[CV20598]
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090177e196ae401e\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 Dec/03/2020

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

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Dec/03/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121112**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:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[Testing facility]
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Dec/03/2020

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

**Form Status:** Not Started

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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 Dec/03/2020

**Form Version:** 06-Jul-2020 21:52

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**Illness Details**

1.	Category of Clinical Event:	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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Dec/03/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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:** 10121112

**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:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Dec/03/2020

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Not Started

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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

090177e196ae401e\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:** 10121112

**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:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/03/2020

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

**Form Status:** Not Started

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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

090177e196ae401e\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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

#	Date:	Vital Signs Details			Form Instance
1.		<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Dec/03/2020

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Not Started

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

#	Date:	Vital Signs Details		Form Instance
1.		<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Dec/03/2020

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

**Form Status:** Not Started

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Dec/03/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Dec/03/2020

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

**Form Status:** Not Started

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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?	

090177e196ae401e\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:** 10121112

**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.					<a href="#">Repeating Pages</a>

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING  
on Dec/03/2020

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

**Form Status:** Not Started

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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/30/2020

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

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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/30/2020
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/30/2020

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

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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/30/2020
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	[BP9JHJ]
5.b	Sample ID	[BRYKJX]
5.c	Sample ID	[BRYKJY]

090177e196ae401e\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:** 10121112

**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Unplanned Assessments**

1.	Assessments	
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**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:** 10121112

**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:** DISPOSITION - FOLLOW-UP

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Not Started

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121112

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	PAROXYSMAL ATRIAL FIBRILLATION	Dec/9/2020 UNK:UNK	NO End Date Time:  Dec/11/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2. DELETED	ADVERSE EVENT	2	DIZZINESS	Dec/9/2020 UNK:UNK	NO End Date Time:  Dec/11/2020 UNK:UNK	<a href="#">Repeating Pages</a>
3. DELETED	ADVERSE EVENT	3	HEART PALPITATIONS	Dec/9/2020 UNK:UNK	NO End Date Time:  Dec/11/2020 UNK:UNK	<a href="#">Repeating Pages</a>
4. DELETED	ADVERSE EVENT	4	TACHYCARDIA	Dec/9/2020 UNK:UNK	NO End Date Time:  Dec/11/2020 UNK:UNK	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	BODY CHILLS	Feb/3/2021 UNK:UNK	NO End Date Time:  Feb/6/2021 UNK:UNK	<a href="#">Repeating Pages</a>
6.	ADVERSE EVENT	6	BODY SWEATS	Feb/3/2021 UNK:UNK	NO End Date Time:  Feb/6/2021 UNK:UNK	<a href="#">Repeating Pages</a>
7.	ADVERSE EVENT	7	BACK PAIN	Feb/3/2021 UNK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae401e\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:** 10121112

**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)	[PAROXYSMAL ATRIAL FIBRILLATION]
4.	Start Date Time:	Dec/9/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/11/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae401e\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:** 10121112

**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

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: [New diagnosis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020492668]

090177e196ae401e\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:** 10121112**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Deleted, Verified**Site Name:** (1012) HOPE Research Institute**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

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

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[DIZZINESS]
4.	Start Date Time:	<del>Dec/9/2020 UNK:UNK</del>
5.	Is the adverse event still ongoing?	NO End Date Time: <del>Dec/11/2020 UNK:UNK</del>
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: [unknown]

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1012

**Subject No:** 10121112

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1012) HOPE Research Institute

**Subject Initials:** ---

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

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

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

090177e196ae401e\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:** 10121112**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Deleted, Verified**Site Name:** (1012) HOPE Research Institute**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[HEART PALPITATIONS]
4.	Start Date Time:	<del>Dec/9/2020 UNK:UNK</del>
5.	Is the adverse event still ongoing?	NO End Date Time: <del>Dec/11/2020 UNK:UNK</del>
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: [unknown]

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1012

**Subject No:** 10121112

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1012) HOPE Research Institute

**Subject Initials:** ---

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

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

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

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1012**Subject No:** 10121112**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Deleted, 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:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[TACHYCARDIA]
4.	Start Date Time:	<del>Dec/9/2020 UNK:UNK</del>
5.	Is the adverse event still ongoing?	NO End Date Time: <del>Dec/11/2020 UNK:UNK</del>
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: [unknown]

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1012

**Subject No:** 10121112

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1012) HOPE Research Institute

**Subject Initials:** ---

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

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

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

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**Header Text:** c4591001

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**Site No:** 1012

**Subject No:** 10121112

**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:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[BODY CHILLS]
4.	Start Date Time:	Feb/3/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/6/2021 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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** c4591001

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**Site No:** 1012

**Subject No:** 10121112

**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

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

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**Subject No:** 10121112

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

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**Site Name:** (1012) HOPE Research Institute

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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)	[BODY SWEATS]
4.	Start Date Time:	Feb/3/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/6/2021 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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** c4591001

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**Subject No:** 10121112

**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

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

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

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**Header Text:** c4591001

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**Site No:** 1012

**Subject No:** 10121112

**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

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1012

**Subject No:** 10121112

**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	[ ]

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**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:** 10121112

**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	<a href="#">Repeating Pages</a>

**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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**Concomitant Medications**

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1012

**Subject No:** 10121112

**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?	

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**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1012

**Subject No:** 10121112

**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

<b>Header Text:</b> c4591001	<b>Form:</b> TRANSFUSIONS
<b>Visit:</b> Logs - Unscheduled	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1012) HOPE Research Institute
<b>Site No:</b> 1012	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10121112	<b>Generated Time (GMT):</b> 29-Mar-2021 04:21
<b>Generated By:</b> pfe.levisse	

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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:** 10121112

**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:** 10121112

**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:	

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**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:** 10121112

**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?	

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**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:** 10121112

**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:** 10121112

**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**Date of Visit**

1.	Date of Visit	Jan/11/2021
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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**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:** 10121112

**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/11/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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:** 10121112

**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:** 10121112

**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:** 10121112

**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:** 10121112

**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:** 10121112

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

**Site No:** 1012

**Subject No:** 10121112

**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	[BRYKKK]
5.b	Sample ID	[BRYKKL]
5.c	Sample ID	[BP9JJC]

090177e196ae401e\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:** 10121112

**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	[BP9JJB]
-----	-----------	----------

090177e196ae401e\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:** 10121112

**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 16:01
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae401e\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:** 10121112

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

**Site No:** 1012

**Subject No:** 10121112

**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	[BR8XCM]
-----	-----------	----------

090177e196ae401e\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:** 10121112

**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 11:51
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

090177e196ae401e\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:** 10121112

**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:** 10121112

**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:** 10121112

**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:** 10121112

**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:** 10121112

**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:** 10121112

**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:** 10121112

**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:** 10121112

**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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
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**Header Text:** c4591001

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

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

**Site No:** 1012

**Subject No:** 10121112

**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-03-2020 19:14:37 (UTC-07:00) Mountain Time (US & Canada)	Selma Leudtke (pfe.sleudtke)	Subject met all inclusion/exclusion criteria Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-14-2021 15:46:37 (UTC-07:00) Mountain Time (US & Canada)	Sahara Vega (pfe.svega)	Met criteria to continue <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Data Complete, Verified

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
Sahara Vega	N/A	Feb-03-2021 09:36:54 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Matthew Doust	Approved	Jan-25-2021 12:28:07 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
---------------	----------	--	------	--------

**Affidavit:**

By my dated signature below, I, MatthewDoust, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

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

Sahara Vega	N/A	Jan-25-2021 09:46:33 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Doust	Approved	Jan-22-2021 09:04:50 (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.

090177e196ae401e\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:** 10121112**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21

Sahara Vega	N/A	Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
<b>Affidavit:</b> N/A				
Matthew Doust	Approved	Dec-10-2020 13:53:07 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
<b>Affidavit:</b> 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	Dec-09-2020 15:19:39 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
<b>Affidavit:</b> N/A				
Matthew Doust	Approved	Dec-09-2020 12:54:02 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
<b>Affidavit:</b> 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	Dec-03-2020 11:04:36 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
<b>Affidavit:</b> 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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Matthew Doust	Approved	Oct-26-2020 16:24:00 (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.

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1012

**Subject No:** 10121112

**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-03-2020 18:46:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 18:46:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1012

**Subject No:** 10121112

**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-03-2020 19:13:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/2/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1012

Subject No: 10121112

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Sep-03-2020 18:46:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10121112	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-03-2020 18:45:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1940	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-03-2020 19:14:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-03-2020 19:14:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A ) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 19:14:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae401e\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:** 10121112

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-03-2020 19:14:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> Sep/2/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1012

**Subject No:** 10121112

**Generated By:** pfe.levissc

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

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

**Site Name:** (1012) HOPE Research Institute

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Sep-03-2020 19:15:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> Sep/2/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-03-2020 19:15:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-03-2020 19:15:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> COMPLETED	Initial Entry

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Header Text: c4591001

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Site No: 1012

Subject No: 10121112

Generated By: pfe.levissc

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1.a

Date	Location	User	Value	Reason
Sep-16-2020 13:41:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> <b>Medical History Term:</b> PROSTATE CA <b>Start Date:</b> Dec/UNK/1987 <b>Ongoing:</b> NO End Date: Dec/UNK/1987	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Feb-22-2021 13:11:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe ratnaa05)	Query 2: Closed	Response satisfies query
Feb-22-2021 11:39:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	Query 2: Answered	Changed data per query
Feb-05-2021 17:19:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe ratnaa05)	Query 2: Opened	Per hospital discharge summary dated 12/11/20 subject had PMH significant for Arrhythmia s/p implantable loop recorder 10/2019, mitral valve prolapse with regurgitation, sleep apnea and tachycardia, please revisit and update the medical history

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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1012**Subject No:** 10121112**Generated By:** pfe.levisse**Form:** GENERAL MEDICAL HISTORY - 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

Jan-27-2021 11:03:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Closed	DQ added to the MH page
Jan-27-2021 10:48:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Opened	Per Discharge summary from Honor Health for the SAE this pt had a history of Arrhythmia and loop recorder implant since October 2019, Mitral Valve prolapse since 2017. Please revisit and update the medical history eCRF page as needed.
Sep-16-2020 13:41:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:41:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> PROSTATE CANCER	Initial Entry

***1.a Start Date:***

Date	Location	User	Value	Reason
Sep-16-2020 13:41:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> Dec/UNK/1987	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Sep-16-2020 13:41:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> NO End Date:	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1012

**Subject No:** 10121112

**Generated By:** pfe.levissc

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

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

**Site Name:** (1012) HOPE Research Institute

**Subject Initials:** ---

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			Dec/UNK/1987	
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***1.b***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-16-2020 13:42:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History:</b> PROSTATECT <b>Term:</b> OMY <b>Start Date:</b> Dec/UNK/1987 <b>Ongoing:</b> NO End Date:  UNK/UNK/ 1987	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:42:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:42:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> PROSTATECTOMY	Initial Entry

***1.b Start Date:***

Date	Location	User	Value	Reason
Sep-16-2020 13:42:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> Dec/UNK/1987	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Sep-16-2020 13:42:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1987	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Sep-16-2020 13:42:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 3 <b>Number:</b> <b>Medical H</b> SQUAMOUS CELL <b>istory Ter</b> CARCINOMA ON F <b>m:</b> ACE <b>Start Date</b> UNK/UNK/2018 :	Initial Entry

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**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1012**Subject No:** 10121112**Generated By:** pfe.levisse**Form:** GENERAL MEDICAL HISTORY - 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**Ongoing:** NO

End Date:

UNK/UNK/2018

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

Date	Location	User	Value	Reason
Sep-16-2020 13:42:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:42:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> SQUAMOUS CELL CARCIN OMA ON FACE	Initial Entry

***I.c Start Date:***

Date	Location	User	Value	Reason
Sep-16-2020 13:42:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***I.c Ongoing:***

Date	Location	User	Value	Reason
Sep-16-2020 13:42:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2018	Initial Entry

***I.d***

Date	Location	User	Value	Reason
Sep-16-2020 13:43:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4	Initial Entry

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			<b>Medical History Term:</b> HYPERLIPID EMIA <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> YES
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***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Sep-16-2020 13:43:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:43:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> HYPERLIPIDEMIA	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Sep-16-2020 13:43:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Sep-16-2020 13:43:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> YES	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Sep-16-2020 13:43:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> VASECTOMY	Initial Entry

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Subject No: 10121112

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			Start Date:	UNK/UNK/1977
			Ongoing:	NO
			End Date:	UNK/UNK/1977

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

Date	Location	User	Value	Reason
Sep-16-2020 13:43:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:43:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<u>Data Entry:</u> VASECTOMY	Initial Entry

**I.e Start Date:**

Date	Location	User	Value	Reason
Sep-16-2020 13:43:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<u>Data Entry:</u> UNK/UNK/1977	Initial Entry

**I.e Ongoing:**

Date	Location	User	Value	Reason
Sep-16-2020 13:43:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<u>Data Entry:</u> NO End Date:  UNK/UNK/1977	Initial Entry

**I.f**

Date	Location	User	Value	Reason
Sep-16-2020 13:43:48	ACV0PFEINFP6000	auto calc	<u>Data Entry:</u>	Initial Entry

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Subject No: 10121112

Generated By: pfe.levissc

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(UTC-07:00) Mountain Time (US & Canada)		(autocalc)	Line/MH Number: 6 Medical History Term: SEASONAL ALLERGIES Start Date: UNK/UNK/2010 Ongoing: YES	
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***If Line/MH Number:***

Date	Location	User	Value	Reason
Sep-16-2020 13:43:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

***If Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-16-2020 13:43:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: SEASONAL ALLERGIES	Initial Entry

***If Start Date:***

Date	Location	User	Value	Reason
Sep-16-2020 13:43:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: UNK/UNK/2010	Initial Entry

***If Ongoing:***

Date	Location	User	Value	Reason
Sep-16-2020 13:43:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Data Entry: YES	Initial Entry

***I.g***

Date	Location	User	Value	Reason
Sep-16-2020 13:44:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7	Initial Entry

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			<b>Medical History Term:</b> LEFT KNEE REPLACEMENT <b>Start Date:</b> UNK/UNK/2014 <b>Ongoing:</b> NO End Date:  UNK/UNK/2014	
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***1.g Line/MH Number:***

Date	Location	User	Value	Reason
Sep-16-2020 13:44:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:44:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> LEFT KNEE REPLACEMENT	Initial Entry

***1.g Start Date:***

Date	Location	User	Value	Reason
Sep-16-2020 13:44:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> UNK/UNK/2014	Initial Entry

***1.g Ongoing:***

Date	Location	User	Value	Reason
Sep-16-2020 13:44:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2014	Initial Entry

***1.h***

Date	Location	User	Value	Reason
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Sep-16-2020 13:48:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N umber:</b> <b>Medical History Term:</b> GENERALIZED OSTEOARTHRITIS <b>Start Date:</b> UNK/UNK/2005 <b>Ongoing:</b> YES	Initial Entry
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***1.h Line/MH Number:***

Date	Location	User	Value	Reason
Sep-16-2020 13:48:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:48:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> GENERALIZED OSTEOARTHRITIS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 13:48:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

***1.h Ongoing:***

Date	Location	User	Value	Reason
Sep-16-2020 13:48:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> YES	Initial Entry

***1.i***

Date	Location	User	Value	Reason
Feb-22-2021 11:37:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe.mmikulak)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9	Changed Information

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			<b>Medical History Term:</b> Heart Arrhythmia <b>Start Date:</b> UNK/UNK/2019 <b>Ongoing:</b> YES	
Feb-22-2021 11:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> Arrhythmia <b>Start Date:</b> UNK/UNK/2019 <b>Ongoing:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 11:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 11:37:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> Heart Arrhythmia	Changed Information
Feb-22-2021 11:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> Arrhythmia	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 11:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Feb-22-2021 11:35:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> YES	Initial Entry

***1.j***

Date	Location	User	Value	Reason
Feb-22-2021 11:36:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 10 <b>ber:</b> <b>Medical Histor</b> Loop Recorder I <b>y Term:</b> mplant <b>Start Date:</b> Oct/UNK/2019 <b>Ongoing:</b> NO End Date:  Oct/UNK/2019	Initial Entry

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Subject No: 10121112

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Feb-22-2021 11:36:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 11:36:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> Loop Recorder Implant	Initial Entry

***1.j Start Date:***

Date	Location	User	Value	Reason
Feb-22-2021 11:36:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> Oct/UNK/2019	Initial Entry

***1.j Ongoing:***

Date	Location	User	Value	Reason
Feb-22-2021 11:36:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> NO End Date:  Oct/UNK/2019	Initial Entry

***1.k***

Date	Location	User	Value	Reason
Feb-22-2021 11:36:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 11 <b>Medical History Term:</b> Mitral Valve Prolapse <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> YES	Initial Entry

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Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Feb-22-2021 11:36:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 11:36:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> Mitral Valve Prolapse	Initial Entry

**I.k Start Date:**

Date	Location	User	Value	Reason
Feb-22-2021 11:36:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**I.k Ongoing:**

Date	Location	User	Value	Reason
Feb-22-2021 11:36:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> YES	Initial Entry

**I.l**

Date	Location	User	Value	Reason
Feb-22-2021 11:37:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 12 <b>Medical History Term:</b> Bilateral hearing loss <b>Start Date:</b> UNK/UNK/1964 <b>Ongoing:</b> YES	Initial Entry

090177e196ae401e\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:** 10121112

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - 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

**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Feb-22-2021 11:37:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 11:37:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> Bilateral hearing loss	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Feb-22-2021 11:37:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> UNK/UNK/1964	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Feb-22-2021 11:37:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae401e\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: 10121112

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-03-2020 19:15:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> Sep/2/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-03-2020 19:15:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> 170.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-03-2020 19:15:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-03-2020 19:15:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> 69.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-03-2020 19:15:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-03-2020 19:15:46 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 25.1	Initial Entry

090177e196ae401e\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: 10121112

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1012) HOPE Research Institute

Subject Initials: ---

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

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Sep-03-2020 19:15:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 97.7 <b>Temperature Unit</b> F : <b>Temperature Loc</b> ORAL CAV <b>ation::</b> ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 19:15:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 19:15:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> 97.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 19:15:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 19:15:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae401e\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:** 10121112

**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-03-2020 19:16:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> Sep/2/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-03-2020 19:16:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> 249283	Initial Entry

090177e196ae401e\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: 10121112

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-03-2020 19:16:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-03-2020 19:16:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-06-2020 10:17:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-04-2020 01:17:11 (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-03-2020 19:16:11 (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-03-2020 19:16:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> YES Date of Collection:  Sep/2/2020	Initial Entry

090177e196ae401e\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: 10121112

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Sep-06-2020 10:17:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Sample ID: BP43SP</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-06-2020 10:17:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BP43SP	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-06-2020 10:17:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Sample ID: BPL1R4</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-06-2020 10:17:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BPL1R4	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-06-2020 10:17:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Sample ID: BPL1R5</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-06-2020 10:17:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BPL1R5	Initial Entry

090177e196ae401e\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: 10121112

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-03-2020 19:16:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-03-2020 19:16:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-06-2020 10:18:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-04-2020 01:18:16 (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-03-2020 19:16:22 (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-03-2020 19:16:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> YES Date of Collection:  Sep/2/2020	Initial Entry

090177e196ae401e\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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a**

Date	Location	User	Value	Reason
Sep-06-2020 10:18:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Sample ID:</b> BP43SN	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-06-2020 10:18:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BP43SN	Initial Entry

090177e196ae401e\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: 10121112

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-03-2020 19:16:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-03-2020 19:16:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-03-2020 19:16:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-03-2020 19:16:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> Sep/2/2020 11:01	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-03-2020 19:16:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-03-2020 19:16:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae401e\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:** 10121112

**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-03-2020 19:16:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-03-2020 19:16:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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-03-2020 19:16:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae401e\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:** 10121112

**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-03-2020 19:16:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> 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:** 10121112

**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 16:02:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

090177e196ae401e\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:** 10121112**Generated By:** pfe.levissc**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[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Sep-21-2020 16:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-21-2020 16:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 96.7 <b>Temperature Unit</b> F : <b>Temperature Loc</b> ORAL CAV <b>ation::</b> ITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-21-2020 16:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-30-2020 01:18:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Sep-29-2020 16:57:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Shana Harshell (pfe.sharshell)	Query 1: Answered	CONFIRM TEMP IS CORRECT
Sep-21-2020 16:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.7 F is outside of Normal Range 97 - 99.5 F.

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 15-Sep-2020 21:54

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Sep-21-2020 16:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> 96.7	Initial Entry
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**2.a Unit:**

Date	Location	User	Value	Reason
Sep-21-2020 16:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-21-2020 16:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae401e\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: 10121112

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 16:02:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-21-2020 16:02:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-29-2020 16:16:07 (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 16:02:49 (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 16:02:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> YES Date of Collection:  Sep/21/2020	Initial Entry

090177e196ae401e\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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a**

Date	Location	User	Value	Reason
Sep-29-2020 16:16:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Shana Harshell (pfe.sharshell)	<b>Data Entry:</b> <b>Sample ID:</b> BP4413	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-29-2020 16:16:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Shana Harshell (pfe.sharshell)	<b>Data Entry:</b> BP4413	Initial Entry

090177e196ae401e\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: 10121112

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 16:04:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-21-2020 16:04:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-21-2020 16:04:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-21-2020 16:04:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> Sep/21/2020 13:13	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-21-2020 16:04:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-21-2020 16:04:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae401e\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:** 10121112

**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-21-2020 16:04:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-21-2020 16:04:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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 16:04:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae401e\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:** 10121112

**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 15:13:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121112

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 15:13:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-20-2020 15:13:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-21-2020 11:36:01 (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 15:13:28 (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 15:13:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> YES Date of Collection:  Oct/20/2020	Initial Entry

090177e196ae401e\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: 10121112

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Oct-21-2020 11:36:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Sample ID: BPL25G</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 11:36:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BPL25G	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-21-2020 11:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Sample ID: BPL25H</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 11:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BPL25H	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 11:36:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Sample ID: BP9JCK</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 11:36:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BP9JCK	Initial Entry

090177e196ae401e\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 Dec/03/2020

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

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-29-2021 14:18:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 5: Closed	Response satisfies query
Jan-29-2021 08:17:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 5: Answered	Changed data per query
Jan-25-2021 15:25:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 5: Reissued:Opened	HOLDS: For Convalescent A1 visit, the lab has received serum sample barcode BP9JHJ; however, the BARCODE nor visit data have been recorded. Please review and update as appropriate. Otherwise please clarify update?
Jan-25-2021 09:47:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 5: Answered	Changed data per query
Jan-13-2021 13:01:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe.riddlj)	Query 5: Opened	HOLDS: For Convalescent A1 visit, the lab has received serum sample barcode BP9JHJ; however, the barcode nor visit data have been recorded. Please review and update as appropriate. Otherwise please clarify.

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Dec/03/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121112**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

Dec-19-2020 08:42:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe ratnaa05)	Query 4: Closed	SAE noted to be entered in AE log
Dec-18-2020 15:13:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe ratnaa05)	Query 4: Opened	Subject is noted to have a reported an episode of Atrial Fibrillation (12/20 /20?), please revisit and update the EDC as soon possible and upload the source in Florence.
Dec-11-2020 00:55:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 3: Closed	Response satisfies query
Dec-10-2020 12:19:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 3: Answered	Changed data per query
Dec-08-2020 04:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe reddy51)	Query 3: Opened	DM: Kindly review and complete 'Microbiology Specimen form' at this visit. Thank you.
Dec-03-2020 11:08:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-03-2020 11:04:35 (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.
Dec-03-2020 11:04:35	ACV0PFEINFP6000	auto query	Query 1: Candidate	Date of Visit is

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Dec/03/2020

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

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-07:00) Mountain Time (US & Canada)		(autoquery)		completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-03-2020 11:04:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Dec/3/2020	Initial Entry

<b>3. COVID-19 Illness Visit:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-03-2020 11:04:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/03/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121112

Subject Initials: ---

Generated By: pfe.lewissc

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Dec/3/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Dec/2/2020	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/03/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121112

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom P</b> YES <b>resent:</b>	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/03/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121112**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**4.c Symptoms:**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> YES	Initial Entry

**4.d Symptoms:**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Jan-14-2021 09:28:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Symptom s:</b> NEW OR INCREASED MUSCLE PAIN	Transcription Error

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/03/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121112

Subject Initials: ---

Generated By: pfe.levisse

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

			Symptom YES Present:	
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom NO Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-19-2021 11:17:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Closed	Response satisfies query
Jan-14-2021 09:28:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-14-2021 09:28:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: YES	Transcription Error
Dec-19-2020 08:33:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Opened	per source dated 12/3/20 Muscle aches is noted. Please revisit and update as needed.
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
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090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/03/2020

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

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Symptoms</b> NEW LOSS OF TAS : TE OR SMELL <b>Symptom</b> NO <b>Present:</b>	Initial Entry
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**4.f Symptoms:**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SME LL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREAS s: ED SORE THROAT <b>Symptom</b> NO <b>Present:</b>	Initial Entry

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/03/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121112

Subject Initials: ---

Generated By: pfe.levisse

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

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> YES	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/03/2020

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

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**4.i Symptoms:**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Dec-03-2020 11:05:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Dec/03/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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Date	Location	User	Value	Reason
Dec-09-2020 15:19:39 (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 Dec/03/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1012

Site Name: (1012) HOPE Research Institute

Subject No: 10121112

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
Dec-09-2020 15:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-09-2020 15:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Dec-09-2020 15:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Dec-09-2020 15:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Dec-09-2020 15:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Dec-09-2020 15:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega	<b>Data Entry:</b> OTHER	Initial Entry

090177e196ae401e\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 Dec/03/2020

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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
Jan-19-2021 11:16:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Closed	source uploaded noted and confirmed the results.
Jan-14-2021 10:47:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Changed data per query
Dec-19-2020 08:39:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Opened	Covid test results are unable for verification, please upload in Florence.
Dec-09-2020 15:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Dec-09-2020 15:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> COVID-19 Swab/Non-Swab (SQ); Sonora Quest Laboratories	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Dec-09-2020 15:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NALT Unknown	Initial Entry

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/03/2020**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:** 10121112**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
Dec-03-2020 11:08:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-03-2020 11:08:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-07-2020 08:41:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-04-2020 00:28:20 (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-03-2020 11:08:50 (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-03-2020 11:08:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES Date of Collection:  Dec/2/2020	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/03/2020

**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a**

Date	Location	User	Value	Reason
Dec-07-2020 08:41:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Sample ID:</b> CV20598	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-07-2020 08:41:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> CV20598	Initial Entry

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/03/2020

**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:** 10121112

**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-03-2020 11:09:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-03-2020 11:09:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-03-2020 11:09:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> 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
Dec-03-2020 11:09:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Telehealth	Initial Entry

090177e196ae401e\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 Dec/03/2020

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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*1.a*

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIA LIST <b>Occurrence of Visits o r Contacts:</b>	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

*1.b*

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Type of Practition</b> EMERGEN <b>er:</b> CY ROOM <b>Occurrence of Visi NO ts or Contacts:</b>	Initial Entry

090177e196ae401e\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 Dec/03/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121112**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
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***I.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

***I.c***

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

***I.d***

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/03/2020

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
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***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae401e\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 Dec/03/2020

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

***I.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***I.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae401e\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 Dec/03/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1012**Site Name:** (1012) HOPE Research Institute**Subject No:** 10121112**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**1.f Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> OTHER	Initial Entry

**1.f Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Dec-03-2020 11:24:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	“Other” is selected , however other specific item is blank. Please review and update as appropriate.
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

**2. Other Type of Practitioner Specify:**

Date	Location	User	Value	Reason
Dec-03-2020 11:24:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Testing facility	Initial Entry

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

Date	Location	User	Value	Reason
Dec-03-2020 11:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Dec/03/2020

**Form Version:** 06-Jul-2020 21:52

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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
Dec-03-2020 11:23:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNES S	Initial Entry

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

Date	Location	User	Value	Reason
Dec-03-2020 11:23:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-03-2020 11:23:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/30/2020

**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:** 10121112

**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 10:48:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

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

Date	Location	User	Value	Reason
Jan-14-2021 10:48:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/30/2020

**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:** 10121112

**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 10:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-14-2021 10:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-25-2021 09:46:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
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 review and correct as appropriate.
Jan-14-2021 10:48:57 (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 10:48:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES Date of Collection:  Dec/30/2020	Initial Entry

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit on Dec/30/2020

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: 10121112

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Jan-25-2021 09:46:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Sample ID: BP9JHJ</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 09:46:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BP9JHJ	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-25-2021 09:47:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Sample ID: BRYKJX</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 09:47:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BRYKJX	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-25-2021 09:47:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Sample ID: BRYKJY</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 09:47:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BRYKJY	Initial Entry

090177e196ae401e\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:** 10121112

**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 15:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-20-2020 15:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-20-2020 15:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae401e\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:** 10121112

**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
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1012

**Subject No:** 10121112

**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

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

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Date	Location	User	Value	Reason
Jan-25-2021 10:17:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Deleted	Secondary to ae #1
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

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

**Form Status:**

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

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Date	Location	User	Value	Reason
Jan-25-2021 10:16:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Deleted	Secondary to ae #1
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1012

**Subject No:** 10121112

**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

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

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Date	Location	User	Value	Reason
Jan-25-2021 10:18:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Deleted	Secondary to ae #1
Jan-25-2021 10:17:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Undeleted	Transcription Error
Jan-25-2021 10:13:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Deleted	Secondary to ae #1
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Created	

090177e196ae401e\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:** 10121112

**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
Feb-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Created	

090177e196ae401e\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:** 10121112

**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-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1012

**Subject No:** 10121112

**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-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Form Created	

090177e196ae401e\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: 10121112

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: ---

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**1. Category:**

Date	Location	User	Value	Reason
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-23-2020 15:56:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Closed	Response satisfies query
Dec-22-2020 16:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	Query 1: Answered	Relevant medical records have been uploaded to Florence.
Dec-19-2020 08:44:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Opened	unable to verify SAE details as no source note to be e-Source in Florence. Please upload all relevant source asap.
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-16-2021 16:01:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-29-2021 08:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Subject confirmed not hispanic. SAE follow-up has been sent.

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1012**Subject No:** 10121112**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

Jan-27-2021 17:37:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical Ethnicity was reported as 'Not Hispanic' on Demography CRF, recorded at the consent visit.
Jan-25-2021 09:49:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Ethnicity will be addressed at next visit, 102
Dec-22-2020 10:05:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Please submit a SAE safety update to report the subject's ethnicity
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> PAROXYSMAL ATRIAL FIB RILLATION	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-16-2021 16:01:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-29-2021 08:20:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	SAE follow-up report with new start date has been faxed as of 1/26/21
Jan-27-2021 17:38:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical Thank you. Please submit a SAE safety FAX to update the SAE start date to 09Dec20 in the SAE as well.
Jan-25-2021 09:52:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-25-2021 09:52:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Dec/9/2020 UNK:UNK	Changed Information

**Header Text:** c4591001

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**Subject No:** 10121112

**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:** ---

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Dec-22-2020 09:57:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical In Vaccine study, SAE start date is day event starts; not day it meets serious criteria (item 11 in vaccine SAE instruct). If SAE event began as non-serious, record the onset date as the date the non-serious event/event symptoms began.
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Dec/10/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-05-2021 17:21:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Closed	new query posted in MH page & unlocked
Jan-27-2021 17:42:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical The Med Hx CRF is currently unfrozen.
Jan-25-2021 09:59:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 1: Answered	Please unfreeze page to add new med history.
Dec-23-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Aloma Ratnasoma (pfe.ratnaa05)	Query 1: Opened	per Hospital discharge summary dated 12/11/20,subject has a PMH significant for arrhythmia s/p implantable loop recorder 10/2019, mitral valve Oprolapse with regurgitation, sleep apnea and tachycardia, please

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

				revisit and update medical history eCRF
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO End Date Time:  Dec/11/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> 3	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Feb-16-2021 16:02:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	SAE update has results of Dec 20, 2020 COVID test
Jan-29-2021 08:23:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	SAE update 26Jan21 does have this information. see page 7 of 8. Listed under laboratory tests (RELEVANT TESTS).
Jan-27-2021 17:41:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical Thank you; however, SAE update (26Jan21) did not include a COVID test, with date and result. Please submit to SAE.

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1012**Subject No:** 10121112**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

Jan-25-2021 10:44:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	Query 2: Answered	Negative. Is being provided on sae follow-up sent today
Dec-22-2020 10:04:41 (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 [#2020492668] to document if COVID testing was performed in hospital (YES/NO or info not available) and if yes, the date and results.
Dec-22-2020 04:28:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE PAROXYSMAL ATRIAL FIBRILLATION: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES Is this serious event associate d with congenital anomaly or birth defect?  NO  Did this serious event result i n death?  NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1012

**Subject No:** 10121112

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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			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.*

Date	Location	User	Value	Reason
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Dec-23-2020 00:25:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lina Gaikwad (pfe.gaikwl)	Query 1: Closed	Response satisfies query
Dec-22-2020 21:09:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Dec-22-2020 16:21:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Dec-22-2020 16:21:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1012**Subject No:** 10121112**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

Time (US & Canada)				
Dec-22-2020 16:21:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  New diagnosis	Initial Entry
Dec-22-2020 10:03:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Event Relationship to study treatment is missing; however, SAE report states that there was not a reasonable possibility that event A fib was related to study treatment. Please review, harmonize reporting, and update where required
Dec-20-2020 22:42:59 (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
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 18:11:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Dec-22-2020 04:28:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quiton)	<b>Data Entry:</b> 2020492668	Initial Entry

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1012**Subject No:** 10121112**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Deleted, Verified**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
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:***(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> DIZZINESS	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Dec/9/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO End Date Time:  Dec/11/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

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Subject No: 10121112

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Date	Location	User	Value	Reason
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> 2	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jan-25-2021 15:10:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	Response satisfies query
Jan-25-2021 10:16:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-25-2021 10:16:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatme nt(s), this event is due to:  OTHER	Initial Entry

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**Header Text:** c4591001

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**Subject No:** 10121112

**Generated By:** pfe.levisse

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			<i>If Other, specify:</i>  unknown	
Dec-20-2020 22:43:39 (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
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

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**Generated By:** pfe.levissc

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Date	Location	User	Value	Reason
Dec-18-2020 18:12:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Initial Entry

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1012**Subject No:** 10121112**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Deleted, Verified**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
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:***(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> HEART PALPITATIONS	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Dec/9/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO End Date Time:  Dec/11/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

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Date	Location	User	Value	Reason
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> 2	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Jan-25-2021 15:12:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Closed	Response satisfies query
Jan-25-2021 10:16:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-25-2021 10:16:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatme nt(s), this event is due to:  OTHER	Initial Entry

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			<i>If Other, specify:</i> unknown	
Dec-20-2020 22:45:00 (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
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

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Date	Location	User	Value	Reason
Dec-18-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> NO	Initial Entry

**Header Text:** c4591001

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**Subject Initials:** ---

**Generated By:** pfe.levisse

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**1. Category:**

Date	Location	User	Value	Reason
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-25-2021 10:42:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 3: Closed	Response satisfies query
Jan-25-2021 10:13:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Secondary to ae #1
Jan-20-2021 11:39:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 2: Closed	clinical: reissued.
Jan-20-2021 11:38:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 3: Opened	clinical: pls confirm this is a separate AE from AE #1-atrial fibrillation Thanks
Jan-06-2021 11:01:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 2: Opened	clinical: pls confirm this is a separate AE from AE #1-atrial fibrillation Thanks

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Jan-06-2021 11:00:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	clinical: reissued.
Dec-21-2020 09:19:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	clinical: pls confirm this is a separate AE from AE #1-atrial fibrillation Thanks
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> TACHYCARDIA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Dec/9/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO End Date Time:  Dec/11/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> 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

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require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-25-2021 15:12:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe frantu)	Query 1: Closed	Response satisfies query
Jan-25-2021 10:18:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-25-2021 10:18:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatme nt(s), this event is due to:  OTHER  If Other, specify:  unknown	Initial Entry
Dec-20-2020 22:45:27 (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.

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Header Text: c4591001

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Generated By: pfe.levissc

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 18:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

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**Subject No:** 10121112

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**1. Category:**

Date	Location	User	Value	Reason
Feb-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-01-2021 13:58:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Closed	Response satisfies query
Feb-22-2021 15:00:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	Query 1: Answered	Related to vaccine reactogenicity
Feb-09-2021 10:42:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: Per Prot Sect 8.1., please review if CHILLS a COVID-19 listed symptoms, start date 1d post Vax 4, is due to vaccine reactogenicity or is more related to Covid-19 (should trigger a COVID Visit and a Nasal Swab collected ASAP)
Feb-08-2021 13:38:13 (UTC-07:00) Mountain	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BODY CHILLS	Initial Entry

090177e196ae401e\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: 10121112

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

Time (US & Canada)

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Feb/3/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO End Date Time:  Feb/6/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> 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-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
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090177e196ae401e\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:** 10121112

**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-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry
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**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-22-2021 23:45:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Feb-22-2021 15:00:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> RELATED	Changed Information
Feb-22-2021 11:41:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-22-2021 11:41:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> NOT RELATED If Not Related to study treat- ment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Unknown	New Information
Feb-09-2021 23:37:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe reddyr51)	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-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

090177e196ae401e\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:** 10121112

**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	Location	User	Value	Reason
Feb-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 13:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae401e\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: 10121112

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-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BODY SWEATS	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Feb/3/2021 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO End Date Time:  Feb/6/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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090177e196ae401e\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: 10121112

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-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-25-2021 00:29:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Shubhada Ghisad (pfe.ghisas)	Query 1: Closed	Response satisfies query
Feb-24-2021 10:29:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-24-2021 10:29:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> RELATED	Initial Entry
Feb-09-2021 23:38:17 (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

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1012

Subject No: 10121112

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

				review and update.
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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 13:38:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae401e\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:** 10121112

**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-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-22-2021 12:17:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (pfe.banchp)	Query 1: Closed	Response satisfies query
Feb-22-2021 11:51:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-22-2021 11:51:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> BACK PAIN	Changed Information
Feb-09-2021 12:00:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (pfe.banchp)	Query 1: Opened	GPDCLIN: subject does not have a record of back pain in MH CRF. Please consider updating MH CRF, otherwise, please clarify. Thank you.
Feb-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> WORSENING OF BACK PAI N	Initial Entry

090177e196ae401e\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:** 10121112

**Generated By:** pfe.levissc

**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

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Feb/3/2021 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> 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-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

090177e196ae401e\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: 10121112

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	Location	User	Value	Reason
Feb-23-2021 04:57:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 1: Closed	closed per data updated.
Feb-22-2021 11:47:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-22-2021 11:47:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe.mmikulak)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatm ent(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Unknown	Changed Information
Feb-09-2021 23:38:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Rajasheshkar 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-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
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090177e196ae401e\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:** 10121112

**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-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Feb-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 13:39:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae401e\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:** 10121112

**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 15:14:15 (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: 10121112

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 15:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-20-2020 15:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-20-2020 15:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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 15:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> Seasonal Influenza Vaccine	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-20-2020 15:14:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Selma Leudtke (pfe.sleudtke)	<b>Data Entry:</b> Oct/16/2020	Initial Entry

090177e196ae401e\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:** 10121112

**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 15:45:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1012

**Subject No:** 10121112

**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 10:05:56 (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 15:45:50 (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 15:45:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> 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

090177e196ae401e\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:** 10121112

**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 10:05:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-20-2021 10:05:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae401e\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:** 10121112

**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 15:46:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1012

**Subject No:** 10121112

**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 15:46:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> 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:** 10121112**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
Feb-23-2021 03:29:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Closed	Query closed data has been updated
Feb-22-2021 15:05:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-22-2021 15:05:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> Jan/13/2021	Transcription Error
Feb-18-2021 00:01:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Opened	Date is reported as 14Jan2021, but subject received vaccination on 13Jan2021. Please confirm the date is correct as entered or update if necessary. Otherwise clarify. Thank you.
Jan-14-2021 15:47:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Jan/14/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-14-2021 15:47:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
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**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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Jan-14-2021 15:47:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> COMPLETED	Initial Entry
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090177e196ae401e\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: 10121112

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 15:47:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-14-2021 15:47:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-20-2021 10:04:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
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 review and correct as appropriate.
Jan-14-2021 15:47:10 (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 15:47:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES Date of Collection:  Jan/13/2021	Initial Entry

090177e196ae401e\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: 10121112

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Jan-20-2021 10:04:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> <b>Sample ID: BRYKKK</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 10:04:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> BRYKKK	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-20-2021 10:04:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> <b>Sample ID: BRYKKL</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 10:04:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> BRYKKL	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-25-2021 11:14:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> <b>Sample ID: BP9JJC</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 11:14:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> BP9JJC	Initial Entry

090177e196ae401e\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: 10121112

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 15:47:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-14-2021 15:47:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-20-2021 10:05:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
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 review and correct as appropriate.
Jan-14-2021 15:47:24 (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 15:47:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES Date of Collection:  Jan/13/2021	Initial Entry

090177e196ae401e\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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a**

Date	Location	User	Value	Reason
Jan-20-2021 10:05:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> <b>Sample ID:</b> BP9JJB	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-20-2021 10:05:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> BP9JJB	Initial Entry

090177e196ae401e\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: 10121112

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 15:47:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-14-2021 15:47:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-14-2021 15:47:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-14-2021 15:47:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Jan/13/2021 16:01	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-14-2021 15:47:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-14-2021 15:47:59 (UTC-07:00) Mountain	ACV0PFEINFP6000	Sahara Vega	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae401e\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: 10121112

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 15:47:48 (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 15:47:48 (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 15:47:48 (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 15:47:48 (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 15:47:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae401e\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:** 10121112

**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 09:36:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Feb/2/2021	Initial Entry

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: 10121112

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
Feb-03-2021 09:37:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-03-2021 09:37:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-08-2021 17:50:02 (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 09:37:05 (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.
Feb-03-2021 09:37:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> YES Date of Collection:  Feb/2/2021	Initial Entry

090177e196ae401e\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:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a**

Date	Location	User	Value	Reason
Feb-08-2021 17:50:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> <b>Sample ID:</b> BR8XCM	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-08-2021 17:50:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> BR8XCM	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1012

Subject No: 10121112

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
Feb-03-2021 09:37:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-03-2021 09:37:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-03-2021 09:37:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-03-2021 09:37:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<b>Data Entry:</b> Feb/2/2021 11:51	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-03-2021 09:37:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-03-2021 09:37:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae401e\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: 10121112

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

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

Date	Location	User	Value	Reason
Feb-03-2021 09:37:36 (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
Feb-03-2021 09:37:36 (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
Feb-03-2021 09:37:36 (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
Feb-03-2021 09:37:36 (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
Feb-03-2021 09:37:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sahara Vega (pfe.svega)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae401e\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:** 10121112

**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-03-2021 08:47:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> Mar/2/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1012

**Subject No:** 10121112

**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-03-2021 08:47:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Mar-03-2021 08:47:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> YES Date of Contact:  Mar/2/2021	Initial Entry

090177e196ae401e\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:** 10121112**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-04-2021 01:19:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ashwini Devi Subhash (pfe.subhaa)	Query 1: Clo sed	Response satisfies query
Mar-03-2021 17:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7588222;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Mar-03-2021 08:48:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe.mmikulak)	<b>Data Entry</b> : Mar/2 /2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-03-2021 08:48:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-03-2021 08:48:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Mikulak (pfe mmikulak)	<b>Data Entry:</b> COMPLETED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1012

Subject No: 10121112

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 15:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-03-2020 19:16:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-03-2020 19:15:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Dec-22-2020 04:31:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	event entered
Dec-17-2020 06:40:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020492668 atrial fibrillation episode(onset date:10Dec2020)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 15:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/20/2020	Initial Entry
Sep-03-2020 19:16:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/2/2020	Initial Entry
Sep-03-2020 19:15:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/2/2020	Initial Entry

090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)				
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090177e196ae401e\Final\Final On: 01-Apr-2021 05:30 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1012

**Site Name:** (1012) HOPE Research Institute

**Subject No:** 10121112

**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 16:02:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Stephanie Catanzaro (pfe.scatanzaro)	<b>Data Entry:</b> Click Here to Enable	Initial Entry