

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/15/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10071347]
2.	Birth Date:	(b) (6)/1952
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: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Oct/15/2020
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: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary artery disease]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cardiac surgery]
	Start Date:	UNK/UNK/2006
	Ongoing:	NO End Date: UNK/UNK/2006
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/2000

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[COPD]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fundoplication]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: UNK/UNK/1989
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Reflux esophagitis]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hepatitis B]
	Start Date:	UNK/UNK/1970
	Ongoing:	NO End Date: UNK/UNK/1973

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hepatitis C]
	Start Date:	UNK/UNK/1999
	Ongoing:	NO End Date: UNK/UNK/2000
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Post-traumatic stress disorder]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[drug allergy Penicillin]
	Start Date:	UNK/UNK/1958
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to food - shellfish]
	Start Date:	UNK/UNK/1952
	Ongoing:	YES

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[drug allergy sulfa]
	Start Date:	UNK/UNK/1958
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Iodine allergy]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Enlarged prostate (benign)]
	Start Date:	Apr/25/2011
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tobacco use disorder, continuous use]
	Start Date:	UNK/UNK/1975
	Ongoing:	YES
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

1 r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypercholesterolemia]
	Start Date:	Nov/25/2011
	Ongoing:	YES

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

eCRF Audit Trail History

Vital Signs

1.	Date:	Oct/15/2020
2.	Weight:	[92.0]
3.	Unit:	kg
4.	Height:	[180.0]
5.	Unit:	cm
6.	Body Mass Index:	[28.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1007
Subject No: 10071347
Generated By: pfe.levisse

Form: RANDOMIZATION
Form Status: Data Complete, Frozen, Verified
Site Name: (1007) Cincinnati Children's Hospital Medical Center
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Oct/15/2020
2.	Randomization Number:	[269840]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/15/2020
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	[BPYV2N]
5.b	Sample ID	[BMRTHD]
5.c	Sample ID	[BMRTHF]

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/15/2020
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	[BPYV2K]
-----	-----------	----------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/15/2020 14:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	Form: REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	Form Status: Data Complete, Frozen, Verified
Site No: 1007	Site Name: (1007) Cincinnati Children's Hospital Medical Center
Subject No: 10071347	Subject Initials: ---
Generated By: pfe.levisse	Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/5/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/5/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[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:	[subject not vaccinated due to SAE]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Form Comments](#)

[eCRF Audit Trail History](#)

Vaccination

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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/3/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/3/2020
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	[BP90JY]
5.b	Sample ID	[BMRWD1]
5.c	Sample ID	[BMRWD4]

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19 **Form Status:** Not Started

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still On going	Form Instance
1.	ADVERSE EVENT	1	atrial fibrillation	Oct/25/2020 11:30	NO End Date Time: Oct/26/2020 UNK:UNK	Repeating Pages

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[atrial fibrillation]
4.	Start Date Time:	Oct/25/2020 11:30
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/26/2020 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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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: [history of coronary artery disease]
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
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	[2020415465]

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Medication Error

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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Concomitant Medications

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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Concomitant Medications

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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

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

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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?	

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Contact Outcome

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/5/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/25/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

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

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[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: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Feb/1/2021
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: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/1/2021
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	[BRB91B]
5.b	Sample ID	[BNWMWV]
5.c	Sample ID	[BNWMWW]

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/1/2021
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	[BRB918]
-----	-----------	----------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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/1/2021 13:18
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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/23/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
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	[BR0ZXS]
-----	-----------	----------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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/23/2021 10:04
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/5/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Robert Frenck	Approved	Mar-09-2021 21:31:24 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, RobertFrenck, 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.

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-15-2020 14:28:15 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	subject not vaccinated due to SAE ----- Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
1	Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	subject not vaccinated due to SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
2	Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	subject not vaccinated due to SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
3	Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	subject not vaccinated due to SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
4	Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	subject not vaccinated due to SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
5	Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	subject not vaccinated due to SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
6	Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	subject not vaccinated due to SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
7	Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	subject not vaccinated due to SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
8	Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	subject not vaccinated due to SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
9	Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	subject not vaccinated due to SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
10	Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	subject not vaccinated due to SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
11	Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	subject not vaccinated due to SAE <hr/> Not Done

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-01-2021 14:55:13 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Robert Frenck	Approved	Mar-09-2021 21:31:24 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, RobertFrenck, 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.

Laura Pace	N/A	Feb-23-2021 10:39:41 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
------------	-----	---	--	-----------------------------------

Affidavit:

N/A

Robert Frenck	Approved	Feb-07-2021 23:03:48 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, RobertFrenck, 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.

Laura Pace	N/A	Feb-01-2021 11:42:52 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
------------	-----	---	--	-----------------------------------

Affidavit:

N/A

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Robert Frenck	Approved	Jan-23-2021 17:42:32 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, RobertFrenck, 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.

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-15-2020 14:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 14:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Oct-15-2020 14:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: OBTAINED Date Written Consent Obtained Oct/15/2020	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-15-2020 14:27:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10071347	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-15-2020 14:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1952	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-15-2020 14:27:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-15-2020 14:27:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 14:27:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: WHITE	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> Oct/15/2020	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-15-2020 14:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Oct/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-15-2020 14:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-15-2020 14:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: COMPLETED	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Oct-29-2020 14:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Line/MH Num 1 ber: Medical Histor Coronary arter y Term: y disease Start Date: UNK/UNK/20 06 Ongoing: YES	Changed Information
Oct-20-2020 12:37:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Line/MH Num 1 ber: Medical Histo Coronary artery ry Term: disease Start Date: UNK/UNK/200 6 Ongoing: NO End Date: UNK/UNK/ 2006	Changed Information
Oct-15-2020 18:37:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 1 ber: Medical Histor Chest pain y Term: Start Date: UNK/UNK/20 06 Ongoing: NO End Date: UNK/UNK /2006	Initial Entry

I.a Line/MH Number:

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Oct-15-2020 18:37:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 12:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 2: Closed	Response satisfies query
Oct-30-2020 11:43:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: Answered	it was updated
Oct-30-2020 02:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 2: Reissued:Opened	Thanks for the response, form has been unfreeze, please update as per below query
Oct-29-2020 13:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 2: Reissued:Candidate	DM: Please unfreeze so site can update this data point
Oct-29-2020 12:28:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: Answered	yes once it is unfrozen
Oct-29-2020 12:04:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 2: Opened	ClinQUERY: Please update stop date per query on AE log.
Oct-21-2020 20:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 1: Closed	Response satisfies query
Oct-20-2020 12:37:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-20-2020 12:37:00 (UTC-05:00) Eastern	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Coronary artery disease	Changed Information

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)				
Oct-18-2020 20:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 1: Opened	ClinQuery: Chest pain: Please can you confirm if a diagnosis is known? If so please update the verbatim term. Thanks
Oct-15-2020 18:37:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Chest pain	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:37:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/2006	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-29-2020 14:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Changed Information
Oct-15-2020 18:37:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO End Date: UNK/UNK/2006	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-15-2020 18:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 2 er: Medical History Cardiac surger Term: y	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

			Start Date: UNK/UNK/2006 Ongoing: NO End Date: UNK/UNK/2006	
--	--	--	--	--

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Cardiac surgery	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/2006	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO End Date: UNK/UNK/2006	Initial Entry

1.c

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Oct-15-2020 18:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Hypertension Start Date: UNK/UNK/1980 Ongoing: YES	Initial Entry
---	-----------------	-------------------------	---	---------------

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Hypertension	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/1980	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

<p>Oct-15-2020 18:39:35 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/MH Number: 4 Medical History Term: Asthma Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/2000</p>	<p>Initial Entry</p>
--	------------------------	---------------------------------	---	----------------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

I.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Asthma	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/1990	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO End Date: UNK/UNK/2000	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-15-2020 18:39:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 r: Medical History: COPD Term: Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:39:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:39:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: COPD	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:39:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/2000	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:39:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Oct-15-2020 18:40:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 6 er: Medical History Fundoplication Term: Start Date: UNK/UNK/19 89	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

			Ongoing: NO	
			End Date:	
			UNK/UNK/ 1989	

1.f Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:40:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:40:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Fundoplication	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:40:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/1989	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:40:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO End Date: UNK/UNK/1989	Initial Entry

1.g

Date	Location	User	Value	Reason
Oct-15-2020 18:41:06 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 7	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)				r: Medical History Reflux esoph Term: agitis Start Date: UNK/UNK/1 989 Ongoing: YES
--------------------	--	--	--	---

I.g Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Reflux esophagitis	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/1989	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Oct-15-2020 18:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 8	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

			er: Medical History Hepatitis B Term: Start Date: UNK/UNK/19 70 Ongoing: NO End Date: UNK/UNK/ 1973	
--	--	--	--	--

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1.h Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Hepatitis B	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/1970	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO End Date: UNK/UNK/1973	Initial Entry

1.i

Date	Location	User	Value	Reason
Oct-15-2020 18:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Hepatitis C Start Date: UNK/UNK/1999	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

			Ongoing: NO End Date: UNK/UNK/ 2000	
--	--	--	---	--

1.i Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Hepatitis C	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/1999	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO End Date: UNK/UNK/2000	Initial Entry

1.j

Date	Location	User	Value	Reason
Oct-15-2020 18:43:31 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 10	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)			Number: Medical History Term: Post-traumatic stress disorder Start Date: UNK/UNK/2016 Ongoing: NO End Date: UNK/UNK/2016	
--------------------	--	--	---	--

1.j Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:43:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:43:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Post-traumatic stress disorder	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:43:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/2016	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:43:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO End Date: UNK/UNK/2016	Initial Entry

1.k

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Oct-15-2020 18:45:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: drug allergy Penicillin Start Date: UNK/UNK/1958 Ongoing: YES	Initial Entry

1.k Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:45:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:45:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: drug allergy Penicillin	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:45:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/1958	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:45:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

1.l

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Oct-15-2020 18:45:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 12 ber: Medical Histo Allergy to food ry Term: - shellfish Start Date: UNK/UNK/195 2 Ongoing: YES	Initial Entry
---	-----------------	-------------------------	---	---------------

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:45:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:45:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Allergy to food - shellfish	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:45:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/1952	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:45:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Oct-15-2020 18:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 Medical History: drug allergy Term: sulfa Start Date: UNK/UNK/1958 Ongoing: YES	Initial Entry
---	-----------------	-------------------------	---	---------------

1.m Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: drug allergy sulfa	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/1958	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

1.n

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Oct-15-2020 18:47:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 14 Medical History Term: Iodine allergy Start Date: UNK/UNK/2006 Ongoing: YES	Initial Entry
---	-----------------	-------------------------	--	---------------

1.n Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 18:47:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 18:47:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Iodine allergy	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 18:47:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/2006	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 18:47:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

1.o

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Oct-29-2020 15:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 15 ber: Medical Histo Enlarged prostat ry Term: e (benign) Start Date: Apr/25/2011 Ongoing: YES	Initial Entry
---	-----------------	-------------------------	--	---------------

I.o Line/MH Number:

Date	Location	User	Value	Reason
Oct-29-2020 15:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 15:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Enlarged prostate (benign)	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Oct-29-2020 15:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Apr/25/2011	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Oct-29-2020 15:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

I.p

Date	Location	User	Value	Reason
Oct-29-2020 15:04:27 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)			Line/MH Number: 16 Medical History Term: Tobacco use disorder, continuous use Start Date: UNK/UNK/1975 Ongoing: YES	
--------------------	--	--	--	--

1.p Line/MH Number:

Date	Location	User	Value	Reason
Oct-29-2020 15:04:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 15:04:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Tobacco use disorder, continuous use	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Oct-29-2020 15:04:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/1975	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
Oct-29-2020 15:04:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

1.q

Date	Location	User	Value	Reason
Nov-02-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Line/MH Number 17	New Information

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

			r: Medical History Depression Term: Start Date: UNK/UNK/ 2016 Ongoing: YES	
Oct-29-2020 15:05:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 17 Medical History Ter Depressio m: n Start Date: Ongoing: YES	Initial Entry

1.q Line/MH Number:

Date	Location	User	Value	Reason
Oct-29-2020 15:05:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 15:05:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Depression	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Nov-03-2020 03:09:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Nov-02-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

I.q Start Date:

Date	Location	User	Value	Reason
Nov-02-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/2016	New Information
Nov-01-2020 23:28:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Please complete this item. Thank you.

I.q Ongoing:

Date	Location	User	Value	Reason
Oct-29-2020 15:05:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

I.r

Date	Location	User	Value	Reason
Oct-29-2020 15:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 18 Medical History Term: Hypercholesterolemia Start Date: Nov/25/2011 Ongoing: YES	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

I.r Line/MH Number:

Date	Location	User	Value	Reason
Oct-29-2020 15:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 15:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Hypercholesterolemia	Initial Entry

I.r Start Date:

Date	Location	User	Value	Reason
Oct-29-2020 15:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Nov/25/2011	Initial Entry

I.r Ongoing:

Date	Location	User	Value	Reason
Oct-29-2020 15:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Oct-15-2020 14:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-15-2020 14:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Oct/15/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-15-2020 14:48:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 92.0	Transcription Error
Oct-15-2020 14:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 53.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-15-2020 14:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-15-2020 14:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 180.0	Transcription Error
Oct-15-2020 14:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 162.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Oct-15-2020 14:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: cm	Initial Entry
---	-----------------	------------------------------	--------------------------	---------------

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-15-2020 14:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28.4	Transcription Error
Oct-15-2020 14:48:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 34.8	Transcription Error
Oct-15-2020 14:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-15-2020 14:49:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier 1 : Temperature: 37.0 Temperature Uni C t: Temperature Loc ORAL CAV ation:: ITY	Transcription Error
Oct-15-2020 14:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier 1 : Temperature: 36.3 Temperature Uni C t: Temperature Loc ORAL CAV ation:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Oct-15-2020 14:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry
---	-----------------	------------------------------	-------------------------	---------------

7.a Temperature:

Date	Location	User	Value	Reason
Oct-15-2020 14:49:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 37.0	Transcription Error
Oct-15-2020 14:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 36.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-15-2020 14:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-15-2020 14:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Oct-15-2020 14:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Oct/15/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-15-2020 14:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 269840	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (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, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071347**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-15-2020 14:49:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-15-2020 14:49:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-15-2020 15:24:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 14:49:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 14:49:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Oct/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 15:24:50 (UTC-05:00) Eastern	ACV0PFEINFP6000	Jesse LePage	Data Entry: Sample ID: BPYV2N	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)		(pfe.jlepage)		
--------------------	--	---------------	--	--

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:24:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BPYV2N	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-15-2020 15:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID: BMRTHD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BMRTHD	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 15:25:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID: BMRTHF	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:25:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BMRTHF	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (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, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-15-2020 14:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-15-2020 14:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-15-2020 15:12:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 14:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 14:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Oct/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 15:12:20 (UTC-05:00) Eastern	ACV0PFEINFP6000	Jesse LePage	Data Entry: Sample ID: BPYV2K	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (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, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)

(pfe.jlepage)

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:12:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BPYV2K	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-15-2020 15:33:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-15-2020 15:33:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-15-2020 15:33:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-15-2020 15:33:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Oct/15/2020 14:40	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-15-2020 15:33:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Oct-15-2020 15:33:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: LEFT	Initial Entry
---	-----------------	------------------------------	----------------------------	---------------

7. Route:

Date	Location	User	Value	Reason
Oct-15-2020 15:33:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-15-2020 15:33:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 15:33:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-15-2020 15:33:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Nov-10-2020 01:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Nov-09-2020 07:16:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	uodated
Nov-09-2020 06:05:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Kindly consider to update missing SWAB PFE, VACIN TRT forms or else clarify. Thank you.
Nov-05-2020 16:30:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Nov/5/2020	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Nov-05-2020 16:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Nov/5/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-05-2020 16:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier: 1 : Temperature: 36.9 Temperature Unit C : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-05-2020 16:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-05-2020 16:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 36.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-05-2020 16:31:14 (UTC-05:00) Eastern	ACV0PFEINFP6000	Laura Pace	Data Entry: C	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1007

Subject No: 10071347

Generated By: pfe.lvisssc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)		(pfe.lpace)	
--------------------	--	-------------	--

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-05-2020 16:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL CAVITY	Initial Entry

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, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-09-2020 07:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-09-2020 07:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-09-2020 07:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 07:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: subject not vaccinated due to SA E	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry
---	-----------------	------------------------------	--------------------------------	---------------

7. Route:

Date	Location	User	Value	Reason
Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 07:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-03-2020 13:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Dec/3/2020	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, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-03-2020 13:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-03-2020 13:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-03-2020 15:50:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 13:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-03-2020 13:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Dec/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-03-2020 15:50:56 (UTC-05:00) Eastern	ACV0PFEINFP6000	Morgan Messeder	Data Entry: Sample ID: BP90JY	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (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, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)		(pfe mmeseder)	
--------------------	--	----------------	--

5.a Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 15:50:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmeseder)	Data Entry: BP90JY	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-03-2020 15:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmeseder)	Data Entry: Sample ID: BMRWD1	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 15:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmeseder)	Data Entry: BMRWD1	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-03-2020 15:51:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmeseder)	Data Entry: Sample ID: BMRWD4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 15:51:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmeseder)	Data Entry: BMRWD4	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: atrial fibrillation	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Oct/25/2020 11:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-27-2020 16:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO End Date Time: Oct/26/2020 UNK:UNK	New Information
Oct-26-2020 16:33:42 (UTC-05:00) Eastern	ACV0PFEINFP6000	Laura Pace	Data Entry: YES	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (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

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)		(pfe.lpace)	
--------------------	--	-------------	--

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 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
Oct-29-2020 09:27:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	SAE report submitted with Neg Covid test result 10/25/20
Oct-29-2020 09:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: Answered	information included in follow up SAE form
Oct-28-2020 05:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 00:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical – Thank you. If NO hospital Covid test was performed is known, please submit this information on a follow-up SAE form, as pertinent information for this trial.
Oct-27-2020 16:48:50 (UTC-05:00) Eastern	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: Answered	covid testing was not done

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)				
Oct-27-2020 15:17:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020415465] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE atrial fibrillation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity?	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

			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
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-29-2020 15:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 2: Closed	Response satisfies query
Oct-29-2020 14:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: Answered	updated
Oct-29-2020 12:08:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 2: Reissued: Opened	query issued on the medhx to unfreeze. please update as appropriate & leave with you

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

				until the page is available to be updated. thanks
Oct-29-2020 11:41:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: Answered	CAD is ongoing, will update med history
Oct-29-2020 09:34:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 2: Opened	ClinQuery:atrial fibrillation: Question 9 states this is related to a previous history of CAD, however, in the medhx, CAD has an end date of 2006. If this was ongoing at baseline, please update as appropriate. Thanks
Oct-28-2020 03:35:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Oct-27-2020 17:13:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	can you please clarify
Oct-27-2020 06:22:22 (UTC-05:00) Eastern Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	Please review "If not related to study treatment other"

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

(US & Canada)				field, the following text was indicated in the comment field [coronary artery disease]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[lv04 SDQ=21183]"
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i>	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

h
i
s
t
o
r
y
o
f
c
o
r
o
n
a
r
y
a
r
t
e
r
y
d
i
s
e
a
s
e

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-02-2020 16:20:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 3: Closed	Response satisfies query
Dec-02-2020 14:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 3: Answered	updated the SAE report

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Dec-02-2020 06:47:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Opened	SAE RECON:AER#2020415465,action taken was updated to DRUG WITHDRAWN in AE CRF while NOT APPLICABLE in Safety database.Please confirm correct action taken. If safety update is required, please submit a follow up form
Dec-01-2020 10:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	Response satisfies query
Dec-01-2020 08:28:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Dec-01-2020 08:28:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: DRUG WITHDRAWN	Changed Information
Nov-30-2020 02:41:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 2: Opened	CLINQUERY: Please review if this AE, Atrial Fibrillation, contributed to decision to end treatment. If so, field to be updated to DRUG WITHDRAWN. If unrelated, please leave as is.
Nov-27-2020 07:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Candidate	CLINQUERY: Please review if this AE, Atrial Fibrillation, contributed to decision to end treatment. If so, field to be updated to DRUG WITHDRAWN. If unrelated, please leave as is.
Oct-27-2020 22:29:01 (UTC-05:00)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Eastern Time (US & Canada)				
Oct-27-2020 16:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-27-2020 16:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT APPLICABLE	Initial Entry
Oct-27-2020 05:40:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotr)	Query 1: Opened	SAE RECON:AER#2020415465 ,action taken was missing in AE CRF while reported as NOT APPLICABLE.Please confirm. If safety update is required, please submit a follow up form

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 05:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotr)	Query 1: Closed	SDB outcome updated to recovered/resolved

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Oct-27-2020 22:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:O pened	SAE RECON 1:Outcome updated in AE CRF as RECOVERED/RESOLVED. Please confirm if a follow up AEM form was sent to update the outcome in Safety database.
Oct-27-2020 16:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-27-2020 16:51:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE atrial fibrillation: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-27-2020 16:51:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-27-2020 16:51:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: RECOVERED/RES OLVED	Changed Information
Oct-27-2020 05:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020415465,outcome was reported as Unknown to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: RECOVERING/RE SOLVING	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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

Date	Location	User	Value	Reason
Oct-26-2020 16:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-28-2020 05:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020415465	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-12-2020 06:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Nov/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-12-2020 06:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-01-2020 10:20:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 3: Closed	Response satisfies query
Dec-01-2020 08:29:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Dec-01-2020 08:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Dec-01-2020 08:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Dec-01-2020 08:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ADVERSE EVENT	Changed Information
Nov-30-2020 01:47:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 3: Opened	CLINQUERY: Per information on page audit, the new onset

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, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

				AFib contributed to the decision to end treatment. If correct, please link the AE (AFib) to this page: Status = ADVERSE EVENT and the AE entry to indicate DRUG WITHDRAWN
Nov-27-2020 07:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 3: Candidate	CLINQUERY: Per information on page audit, the new onset AFib contributed to the decision to end treatment. If correct, please link the AE (AFib) to this page: Status = ADVERSE EVENT and the AE entry to indicate DRUG WITHDRAWN
Nov-13-2020 09:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 2: Closed	Response satisfies query
Nov-13-2020 07:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: Answered	updated
Nov-13-2020 06:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 2: Opened	Clin: EOT states the primary reason for discontinuation is A-Fib. Please update Q3 as appropriate. Thanks
Nov-12-2020 18:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-12-2020 06:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is NO LONGER MEETS

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (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, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

				ELIGIBILITY CRITERIA but "Specify Status" is missing.
Nov-12-2020 06:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO LONGER MEETS ELIGIBILITY CRITERIA	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Dec-01-2020 08:29:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry:	Changed Information
Nov-14-2020 10:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Closed	Response satisfies query
Nov-14-2020 09:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-14-2020 09:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: subject did not meet inclusion criteria #3	Changed Information
Nov-14-2020 07:56:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Opened	Clin: If subject is a screen fail, or has met an inclusion criterion, please update to state subject DID NOT MEET IC3. Further, please confirm if subject will remain in safety FU. Thanks
Nov-13-2020 07:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: meets inclusion criteria #3	Changed Information
Nov-12-2020 18:41:03 (UTC-05:00) Eastern	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Participant has new onset Atria	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (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, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)			1 fib with current heart halter monitor, unstable medical condition	
--------------------	--	--	---	--

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-01-2021 11:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Dec/23/2020	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-01-2021 11:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national reco mmendations and confirmed t o have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.lvisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-01-2021 11:42:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/25/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-01-2021 11:42:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-01-2021 14:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> Feb/1/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Feb-01-2021 14:55:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Feb/1/2021	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-01-2021 14:01:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	Data Entry: Feb/1/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-01-2021 14:01:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-01-2021 14:01:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	Data Entry: COMPLETED	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071347**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-01-2021 14:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-01-2021 14:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-01-2021 14:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 14:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-01-2021 14:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	Data Entry: YES Date of Collection: Feb/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-01-2021 14:05:55	ACV0PFEINFP6000	Morgan	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

(UTC-05:00) Eastern
Time (US & Canada)

Messeder
(pfe mmeseder)

Sample ID: BRB91B

5.a Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 14:05:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmeseder)	Data Entry: BRB91B	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-01-2021 14:06:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmeseder)	Data Entry: Sample ID: BNWMWV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 14:06:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmeseder)	Data Entry: BNWMWV	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-01-2021 14:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmeseder)	Data Entry: Sample ID: BNWMWV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 14:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmeseder)	Data Entry: BNWMWV	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071347**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-01-2021 14:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-01-2021 14:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-01-2021 14:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 14:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-01-2021 14:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	Data Entry: YES Date of Collection: Feb/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-01-2021 14:02:18	ACV0PFEINFP6000	Morgan	Data Entry:	Initial Entry

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

(UTC-05:00) Eastern
Time (US & Canada)

Messeder
(pfe mmesseder)

Sample ID: BRB918

5.a Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 14:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	Data Entry: BRB918	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-01-2021 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-01-2021 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-01-2021 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-01-2021 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Feb/1/2021 13:18	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-01-2021 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Feb-01-2021 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: LEFT	Initial Entry
---	-----------------	------------------------------	----------------------------	---------------

7. Route:

Date	Location	User	Value	Reason
Feb-01-2021 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-01-2021 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-01-2021 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-01-2021 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-01-2021 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 10:39:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> Feb/23/2021	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071347**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-23-2021 10:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 10:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-23-2021 10:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 10:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-23-2021 10:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Feb/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-23-2021 10:50:03 (UTC-05:00) Eastern	ACV0PFEINFP6000	Morgan Messeder	Data Entry: Sample ID: BR0ZXS	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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)

(pfe mmesseder)

5.a Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 10:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	Data Entry: BR0ZXS	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-23-2021 10:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-23-2021 10:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-23-2021 10:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-23-2021 10:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Feb/23/2021 10:04	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-23-2021 10:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Feb-23-2021 10:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: RIGHT	Initial Entry
---	-----------------	------------------------------	-----------------------------	---------------

7. Route:

Date	Location	User	Value	Reason
Feb-23-2021 10:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-23-2021 10:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-23-2021 10:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-23-2021 10:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 10:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071347

Generated By: pfe.levisse

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Dec-01-2020 08:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Changed Information
Nov-12-2020 06:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-15-2020 14:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-15-2020 14:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-01-2020 08:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/5/2020	Changed Information
Nov-12-2020 06:55:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/5/2020	Initial Entry
Oct-15-2020 14:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/15/2020	Initial Entry
Oct-15-2020 14:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/15/2020	Initial Entry

090177e196ae4028\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071347

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Jan-22-2021 07:44:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Click Here to Enable	Initial Entry