

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** COHORT\_SELECTION

**Form Status:** Data Complete, Locked, 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](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Locked, 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 Aug/27/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10071280]
2.	Birth Date:	(b) (6)/1982
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, 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	Aug/27/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, 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 _____
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**Exclusion Criteria Met**

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

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

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, 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	Aug/27/2020
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: 10071280

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, 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:	[Kidney stones]
	Start Date:	Nov/UNK/2019
	Ongoing:	NO End Date: Aug/4/2020
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Lithotripsy]
	Start Date:	Nov/UNK/2019
	Ongoing:	NO End Date: Nov/UNK/2019
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Pyeloplasty]
	Start Date:	Aug/4/2020
	Ongoing:	NO End Date: Aug/4/2020
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	UNK/UNK/1997
	Ongoing:	YES

090177e196ae4027\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: 10071280

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, 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:	[Seasonal allergy]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergic to cats]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dust allergy]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sleeve gastrectomy]
	Start Date:	May/UNK/2019
	Ongoing:	NO End Date: May/UNK/2019
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Overweight]
	Start Date:	UNK/UNK/1996
	Ongoing:	NO End Date: Jun/UNK/2020

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**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, 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:	Aug/27/2020
2.	Weight:	[75.4]
3.	Unit:	kg
4.	Height:	[174.0]
5.	Unit:	cm
6.	Body Mass Index:	[24.9]

**Vital Signs Details**

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, 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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/27/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> RANDOMIZATION
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1007) Cincinnati Children's Hospital Medical Center
<b>Site No:</b> 1007	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10071280	<b>Generated Time (GMT):</b> 29-Mar-2021 04:12
<b>Generated By:</b> pfe.levisse	

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Aug/27/2020
2.	Randomization Number:	[68493]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, 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: Aug/27/2020
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	[BP75JJ]
5.b	Sample ID	[BP75JK]
5.c	Sample ID	[BP75JL]
5.d	Sample ID	[BPG0F5]
5.e	Sample ID	[BPG0F6]

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**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Locked, 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: Aug/27/2020
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	[BP75J8]
-----	-----------	----------

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L **Form:** VACCINATION  
**Form Version:** 22-Apr-2020 21:04 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center  
**Subject No:** 10071280 **Subject Initials:** ---  
**Generated By:** pfe.levisse **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:	Aug/27/2020 10:14
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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> REACTOGENICITY DIARY
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 06-Jul-2020 21:53	<b>Site Name:</b> (1007) Cincinnati Children's Hospital Medical Center
<b>Site No:</b> 1007	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10071280	<b>Generated Time (GMT):</b> 29-Mar-2021 04:12
<b>Generated By:</b> pfe.levisse	

[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:** 10071280

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, 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	Sep/23/2020
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Locked, 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:	Sep/23/2020
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**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, 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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/23/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Locked, 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: Sep/23/2020
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	[BPYTSJ]
-----	-----------	----------

090177e196ae4027\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:** 10071280

**Generated By:** pfe.levisse

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, 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?	YES Date of First Delay: Sep/17/2020  Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/23/2020 09:15
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**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	Oct/21/2020
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, Locked, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071280

**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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[samples are in convalescent visit]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020      **Form:** DATE OF VISIT - ILLNESS ONSET

**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:** 10071280

**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	Sep/17/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19**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:** 10071280**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**eCRF Audit Trail History****Signs and Symptoms**

1.	Date of Assessment:	Sep/17/2020
2.	Date of First Symptom Started:	Sep/12/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Sep/17/2020

**Symptoms**

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

**Symptoms - Other**

5.a	Symptoms - Other Text:	[headache]
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**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Microbiology Specimen**

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020      **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

**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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[subject came in for visit]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020      **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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: Sep/17/2020
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	[BPYTR6]
-----	-----------	----------

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** HEALTH CARE UTILIZATION

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Respiratory Treatment**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** ILLNESS DETAILS

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Illness Details**

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



**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** ILLNESS DETAILS - SEVERE

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Illness Details**

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

**Header Text:** c4591001

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

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test :	Result:	<a href="#">Repeating Pages</a>

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Lab Chemistry Details**

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

**Lab Result**

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Laboratory Data Hematology**

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

**Lab Result**

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID  
Sep/17/2020

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Vital Signs**

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

**Vital Signs Details**

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



**Header Text:** c4591001

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

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** OXYGENATION PARAMETERS

**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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Oxygenation Parameters**

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

**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1007

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

**Subject No:** 10071280

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Concomitant Medications**

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING  
Sep/17/2020

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Imaging**

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT  
on Oct/21/2020

**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:** 10071280

**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	Oct/21/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY on Oct/21/2020

**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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYV5B]
5.b	Sample ID	[BMRTL B]
5.c	Sample ID	[BMRTL C]

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/21/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levissc

**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:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.leviscc

**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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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	[ ]
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**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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Muscle Soreness in arm of injection	Jan/28/2021 20:00	NO End Date Time:  Jan/30/2021 08:00	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	bilateral deep cervical swollen lymph nodes	Feb/18/2021 08:00	NO End Date Time:  Feb/25/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae4027\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:** 10071280

**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

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Muscle Soreness in arm of injection]
4.	Start Date Time:	Jan/28/2021 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/30/2021 08:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO

090177e196ae4027\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:** 10071280

**Generated By:** pfe.lewissc

**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

15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**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

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[bilateral deep cervical swollen lymph nodes]
4.	Start Date Time:	Feb/18/2021 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/25/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

090177e196ae4027\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:** 10071280

**Generated By:** pfe.lewissc

**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

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

090177e196ae4027\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:** 10071280

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.lewissc

**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	[ ]

090177e196ae4027\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:** 10071280

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.lewissc

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**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.	Date:	//

090177e196ae4027\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:** 10071280

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.lewissc

**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?	

090177e196ae4027\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:** 10071280

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.lewissc

**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?	

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**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:	//

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:** 10071280

**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:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

**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:** 10071280

**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?	

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME - MONTH 1
<b>Visit:</b> Unplanned Vaccination - Unscheduled	<b>Form Status:</b> Not Started
<b>Form Version:</b> 10-Oct-2020 15:57	<b>Site Name:</b> (1007) Cincinnati Children's Hospital Medical Center
<b>Site No:</b> 1007	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10071280	<b>Generated Time (GMT):</b> 29-Mar-2021 04:12
<b>Generated By:</b> pfe.levisse	

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:** 10071280

**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:** 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:** 10071280

**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/24/2020
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, Verified

**Site No:** 1007

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

**Subject No:** 10071280

**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
----	---	---

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.lewissc

**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/27/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Withdrawal Of Consent**

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

**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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 10071280

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, 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	Jan/28/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Data Complete, Locked, 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 Jan/28/2021
----	--------------	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Locked, 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:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Status:** Data Complete, Locked, 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 for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Jan/28/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, 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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/28/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae4027\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:** 10071280

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, 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: Jan/28/2021
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	[BRB8ZX]
5.b	Sample ID	[BNWMW6]
5.c	Sample ID	[BNWMW8]

090177e196ae4027\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:** 10071280

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Locked, 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: Jan/28/2021
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	[BRB900]
-----	-----------	----------

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:	Jan/28/2021 13:14
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

090177e196ae4027\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:** 10071280

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, 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/17/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, 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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/17/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Locked, 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/17/2021
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	[BR0ZR5]
-----	-----------	----------

090177e196ae4027\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:** 10071280

**Generated By:** pfe.levisse

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, 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/17/2021 13:35
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

090177e196ae4027\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:** 10071280

**Generated By:** pfe.lewissc

**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:** 10071280

**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:** 10071280

**Generated By:** pfe.lewissc

**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:** 10071280

**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:** 10071280

**Generated By:** pfe.levissc

**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	

<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME
<b>Visit:</b> V105_MONTH18	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:04	<b>Site Name:</b> (1007) Cincinnati Children's Hospital Medical Center
<b>Site No:</b> 1007	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10071280	<b>Generated Time (GMT):</b> 29-Mar-2021 04:12
<b>Generated By:</b> pfe.levisse	

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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:** 10071280

**Generated By:** pfe.levissc

**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	FOLLOW-UP
2.	Subject Status Date	Oct/21/2020

**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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**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:** 10071280

**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-08-2021 22:50:53 (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.



**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levissc

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

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Aug-27-2020 10:31:03 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
Form	Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
1	Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
2	Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
3	Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
4	Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
5	Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
6	Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
7	Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
8	Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
9	Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
Form	Jan-28-2021 13:51:28 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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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-08-2021 22:50:53 (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.

Haley Muth	N/A	Feb-17-2021 13:40:01 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Robert Frenck	Approved	Jan-29-2021 22:57:13 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**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	Jan-28-2021 13:50:35 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Robert Frenck	Approved	Oct-28-2020 18:26:06 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

**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.

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levissc

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-27-2020 10:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 10:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-27-2020 10:00:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/27/2020	Initial Entry



Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.levisse

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-27-2020 10:00:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10071280	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-27-2020 10:00:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1982	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-27-2020 10:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-27-2020 10:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 10:00:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae4027\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:** 10071280

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-27-2020 10:01:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Aug/27/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Locked, 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
Aug-27-2020 10:31:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Aug/27/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-27-2020 10:31:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-27-2020 10:31:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4027\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: 10071280

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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*I.a*

Date	Location	User	Value	Reason
Aug-27-2020 10:34:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Kidney stones <b>Start Date:</b> Nov/UNK/2019 <b>Ongoing:</b> NO End Date: Aug/4/2020	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-27-2020 10:34:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 10:34:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Kidney stones	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Aug-27-2020 10:34:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Nov/UNK/2019	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Aug-27-2020 10:34:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO End Date: Aug/4/2020	Initial Entry

090177e196ae4027\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: 10071280

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

**I.b**

Date	Location	User	Value	Reason
Aug-27-2020 10:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 2 Medical History Term: Lithotripsy Start Date: Nov/UNK/2019 Ongoing: NO End Date: Nov/UNK/2019	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 10:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 10:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Lithotripsy	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Aug-27-2020 10:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Nov/UNK/2019	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Aug-27-2020 10:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO End Date: Nov/UNK/2019	Initial Entry

**I.c**

Date	Location	User	Value	Reason
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090177e196ae4027\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: 10071280

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Aug-27-2020 10:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term</b> Pyeloplasty : <b>Start Date:</b> Aug/4/2020 <b>Ongoing:</b> NO End Date:  Aug/4/2020	Initial Entry
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**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-27-2020 10:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 10:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Pyeloplasty	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-27-2020 10:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Aug/4/2020	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-27-2020 10:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO End Date:  Aug/4/2020	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-27-2020 10:36:01 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4	Initial Entry

090177e196ae4027\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: 10071280

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

(US & Canada)			<b>Medical History Term:</b> Asthma <b>Start Date:</b> UNK/UNK/1997 <b>Ongoing:</b> YES	
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**I.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-27-2020 10:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 10:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Asthma	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Aug-27-2020 10:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> UNK/UNK/1997	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Aug-27-2020 10:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Aug-27-2020 10:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> Seasonal allergy <b>Start Date:</b> UNK/UNK/1990 <b>Ongoing:</b> YES	Initial Entry

090177e196ae4027\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: 10071280

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Aug-27-2020 10:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 10:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Seasonal allergy	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Aug-27-2020 10:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Aug-27-2020 10:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Aug-27-2020 10:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> Allergic to cats <b>Start Date:</b> UNK/UNK/1990 <b>Ongoing:</b> YES	Initial Entry

090177e196ae4027\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: 10071280

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Aug-27-2020 10:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 10:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Allergic to cats	Initial Entry

***I.f Start Date:***

Date	Location	User	Value	Reason
Aug-27-2020 10:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

***I.f Ongoing:***

Date	Location	User	Value	Reason
Aug-27-2020 10:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

***I.g***

Date	Location	User	Value	Reason
Aug-27-2020 10:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> Dust allergy <b>Start Date:</b> UNK/UNK/1990 <b>Ongoing:</b> YES	Initial Entry

090177e196ae4027\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: 10071280

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

*I.g Line/MH Number:*

Date	Location	User	Value	Reason
Aug-27-2020 10:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 10:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Dust allergy	Initial Entry

*I.g Start Date:*

Date	Location	User	Value	Reason
Aug-27-2020 10:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

*I.g Ongoing:*

Date	Location	User	Value	Reason
Aug-27-2020 10:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

*I.h*

Date	Location	User	Value	Reason
Aug-27-2020 10:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8 <b>Medical History Term:</b> Sleeve gastrectomy <b>Start Date:</b> May/UNK/2019 <b>Ongoing:</b> NO End Date:  May/UNK/2019	Initial Entry

090177e196ae4027\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: 10071280

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Aug-27-2020 10:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 10:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sleeve gastrectomy	Initial Entry

**I.h Start Date:**

Date	Location	User	Value	Reason
Aug-27-2020 10:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> May/UNK/2019	Initial Entry

**I.h Ongoing:**

Date	Location	User	Value	Reason
Aug-27-2020 10:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO End Date:  May/UNK/2019	Initial Entry

**I.i**

Date	Location	User	Value	Reason
Aug-27-2020 10:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 9 Medical History Ter Overweight m: Start Date: UNK/UNK/199 6 Ongoing: NO End Date:  Jun/UNK/20 20	Initial Entry

090177e196ae4027\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: 10071280

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Aug-27-2020 10:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 10:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Overweight	Initial Entry

***L.i Start Date:***

Date	Location	User	Value	Reason
Aug-27-2020 10:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> UNK/UNK/1996	Initial Entry

***L.i Ongoing:***

Date	Location	User	Value	Reason
Aug-27-2020 10:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO End Date:  Jun/UNK/2020	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1007

Subject No: 10071280

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Aug/27/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 75.4	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 174.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 24.9	Initial Entry

**7.a**

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1007

Subject No: 10071280

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Aug-27-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 37.0 <b>Temperature Unit:</b> C <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 37.0	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> C	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:49

Site No: 1007

Subject No: 10071280

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Aug/27/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 <b>Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 21-Aug-2020 02:49  
**Site No:** 1007  
**Subject No:** 10071280  
**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1007) Cincinnati Children's Hospital Medical Center  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:12

			<b>Result::</b> NEGATIVE <b>Not Done::</b>	
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-27-2020 10:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae4027\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: 10071280

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-27-2020 10:33:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Aug/27/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-31-2020 04:05:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Aug-28-2020 12:22:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-28-2020 12:22:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 68493	Transcription Error
Aug-28-2020 09:01:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	As per Impala, Randomization Number is 68493 . Please review and update as appropriate. "[newtod07 SDQ=1861]"
Aug-27-2020 10:33:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 48493	Initial Entry

090177e196ae4027\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, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.lewissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-27-2020 10:31:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-27-2020 10:31:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-27-2020 14:03:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 10:31:34 (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.
Aug-27-2020 10:31:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection:  Aug/27/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-27-2020 14:03:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BP75JJ	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-27-2020 14:03:41	ACV0PFEINFP6000	Jesse	<b>Data Entry:</b>	Initial Entry

090177e196ae4027\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: 10071280  
 Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
 Audit Trail History  
 Form Status: Data Complete, Locked, Frozen, Verified  
 Site Name: (1007) Cincinnati Children's Hospital Medical Center  
 Subject Initials: ---  
 Generated Time (GMT): 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)		LePage (pfe.jlepage)	BP75JJ	
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**5.b**

Date	Location	User	Value	Reason
Aug-27-2020 14:03:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<u>Data Entry:</u> Sample ID: BP75JK	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-27-2020 14:03:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<u>Data Entry:</u> BP75JK	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-27-2020 14:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<u>Data Entry:</u> Sample ID: BP75JL	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-27-2020 14:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<u>Data Entry:</u> BP75JL	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-27-2020 14:08:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<u>Data Entry:</u> Sample ID: BPG0F5	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-27-2020 14:08:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<u>Data Entry:</u> BPG0F5	Initial Entry

090177e196ae4027\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, Locked, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

*5.e*

Date	Location	User	Value	Reason
Aug-27-2020 14:08:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BPG0F6	Initial Entry

*5.e Sample ID*

Date	Location	User	Value	Reason
Aug-27-2020 14:08:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BPG0F6	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.lewissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-27-2020 10:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-27-2020 10:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-27-2020 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 10:31:42 (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.
Aug-27-2020 10:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection:  Aug/27/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-27-2020 14:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BP75J8	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-27-2020 14:00:21	ACV0PFEINFP6000	Jesse	<b>Data Entry:</b>	Initial Entry

090177e196ae4027\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, Locked, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time  
(US & Canada)

LePage  
(pfe.jlepage) BP75J8

090177e196ae4027\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: 10071280

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-27-2020 10:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-27-2020 10:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-27-2020 10:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-27-2020 10:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Aug/27/2020 10:14	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-27-2020 10:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-27-2020 10:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

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090177e196ae4027\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:** 10071280

**Generated By:** pfe.lewissc

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, 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
Aug-27-2020 10:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-27-2020 10:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSE RVATION 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
Aug-27-2020 10:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4027\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:** 10071280

**Generated By:** pfe.levisse

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-27-2020 10:48:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-23-2020 08:56:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 15-Sep-2020 21:54**Site No:** 1007**Subject No:** 10071280**Generated By:** pfe.levisse**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Locked, 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
Sep-23-2020 08:56:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 37.0 <b>Temperature Unit:</b> C <b>Temperature Locatio</b> <b>n::</b> ORAL CAVIT Y	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 37.0	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:38 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

(US & Canada)				
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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:49

Site No: 1007

Subject No: 10071280

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 <b>Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

			<b>Result::</b> NEGATIVE	
			<b>Not Done::</b>	

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.lewissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-23-2020 08:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-23-2020 11:38:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 08:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-23-2020 08:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection: Sep/23/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-23-2020 11:38:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BPYTSJ	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-23-2020 11:38:03	ACV0PFEINFP6000	Jesse	<b>Data Entry:</b>	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time  
(US & Canada)

LePage  
(pfe.jlepage)

BPYTSJ

090177e196ae4027\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: 10071280

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-23-2020 10:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of First Delay:  Sep/17/2020  Reason(s) for Temporary Delay of Vaccination  FEVER OR ACUTE ILLNESS	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-23-2020 10:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-23-2020 10:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-23-2020 10:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/23/2020 09:15	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-23-2020 10:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae4027\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:** 10071280

**Generated By:** pfe.levissc

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

Sep-23-2020 10:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Sep-23-2020 10:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-23-2020 10:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 10:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4027\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:** 10071280

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Oct-24-2020 03:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nikita Singh (pfe.singhn98)	Query 1: Clo sed	Response satisfies query
Oct-23-2020 09:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Query 1: Ans wered	Subject had a combined Visit 3 and Convalescent Visit
Oct-23-2020 02:16:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW5123368;The Date of Visit at Visit V3_MONTH1_POSTVAX2_L is the same as the other Date of Visit at Visit COVID_A1. Please review for duplication and update as appropriate.
Oct-21-2020 10:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry</b> : Oct/21 /2020	Initial Entry

090177e196ae4027\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, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.lewissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-21-2020 10:10:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-21-2020 10:10:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-21-2020 10:10:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 10:10:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> samples are in convalescent visit	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071280**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
Sep-17-2020 10:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-17-2020 10:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Sep-17-2020 10:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Sep-17-2020 10:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/17/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 05:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sharat Nair (pfe.nairs51)	Query 1: Closed	Response satisfies query
Oct-07-2020 07:34:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	subject was referring to past of symptoms because that is how the question is asked on the covid illness diary. "Did you have any symptoms in the past week?"

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Sep-29-2020 04:00:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonali shah (pfe.shahs132)	Query 1: Opened	As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 18SEP2020. But there is COVID Illness visit reported in the database for 17SEP2020. Please clarify
Sep-17-2020 10:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/17/2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/12/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Nov-04-2020 01:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Response satisfies query
Nov-03-2020 15:18:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	18sep2020 is the day subject responded to the question on the diary which as in the past week did you experience any symptoms
Nov-03-2020 01:16:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Reissued:Opened	RQ1: Response states 'not a new event; this was the 17sep2020 event'. Please confirm if Illness edairy entry on 18SEP2020 was deemed erroneous. Please update or clarify.
Nov-02-2020 10:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	reviewed this is not a new event; this was the 17sep2020 event
Oct-31-2020 08:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonali shah (pfe.shahs132)	Query 1: Opened	Illness eDiary: Per COVID illness diary 18SEP2020 was

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020  
**Form Version:** 15-Sep-2020 21:55  
**Site No:** 1007  
**Subject No:** 10071280  
**Generated By:** pfe.levisse

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

				reported as Yes and symptoms ongoing is reported with date as 17SEP2020. Please review and confirm if 18SEP2020 reported is new event in comment.
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Sep/17/2020	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> NO	Initial Entry



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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:** 10071280**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12**4.b Symptoms:**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED S s: HORTNESS OF BREATH <b>Symptom</b> NO <b>Present:</b>	Initial Entry

**4.c Symptoms:**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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:** 10071280**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12**4.d Symptoms:**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Sep-17-2020 10:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom P NO</b> <b>resent:</b>	Initial Entry
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom P</b> <b>resent:</b>	Initial Entry

**4.e Symptoms:**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAI N	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Sep-17-2020 10:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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: 10071280

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL <b>Symptom P</b> NO <b>resent:</b>	Initial Entry
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**4.f Symptoms:**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SORE THROAT <b>Symptom P</b> YES <b>resent:</b>	Initial Entry

**4.g Symptoms:**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEW OR INCREASED SORE THRO AT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

**4.h**

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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:** 10071280**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry

**4.h Symptoms:**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

**4.i Symptoms:**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Sep-17-2020 10:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020  
**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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:** 10071280  
**Subject Initials:** ---  
**Generated By:** pfe.levisse  
**Generated Time (GMT):** 29-Mar-2021 04:12

Sep-17-2020 10:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptoms - Other:</b> headache	Initial Entry
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**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Sep-17-2020 10:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> headache	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Done	Initial Entry

**7. Test Result:**

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Date	Location	User	Value	Reason
Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 10:55:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.lewissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-17-2020 10:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-17-2020 10:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-17-2020 12:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-17-2020 12:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Sep-17-2020 10:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 10:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> subject came in for visit	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-17-2020 12:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)



**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center  
**Subject No:** 10071280 **Subject Initials:** ---  
**Generated By:** pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

Sep-17-2020 12:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BPYTR6	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-17-2020 12:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-17-2020 12:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b>	Changed Information
Sep-17-2020 12:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 7 characters in length. Please review and correct as appropriate.
Sep-17-2020 12:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BPYTR6	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.lewissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-17-2020 10:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-17-2020 10:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-17-2020 12:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 10:47:15 (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.
Sep-17-2020 10:47:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection: Sep/17/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-17-2020 12:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BPYTR6	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-17-2020 12:56:16	ACV0PFEINFP6000	Jesse	<b>Data Entry:</b>	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time  
(US & Canada)

LePage  
(pfe.jlepage)

BPYTR6

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.levissc

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

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*I.a*

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071280**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

***I.c***

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

***I.d***

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071280**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12***I.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> URGENT CARE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

***I.e***

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CO NSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHE R <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

*1.f Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> OTHER	Initial Entry

*1.f Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Sep-17-2020 10:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 10:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/17/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Sep-17-2020 15:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 15:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-17-2020 15:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Oct/21/2020 **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071280**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
Oct-24-2020 07:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Clo sed	Response satisfies query
Oct-23-2020 09:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Query 1: Ans wered	Subject had a combined Visit 3 and Convalescent Visit
Oct-23-2020 02:16:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW5123367;The Date of Visit at Visit COVID_A1 is the same as the other Date of Visit at Visit V3_MONTH1_POSTVAX2_L. Please review for duplication and update as appropriate.
Oct-21-2020 10:09:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry</b> : Oct/2 1/202 0	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 10:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> COVID_A1	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
on Oct/21/2020 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:** 10071280**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-21-2020 10:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-21-2020 10:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-21-2020 10:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 10:09:30 (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-21-2020 10:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection:  Oct/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-21-2020 10:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BPYV5B	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-21-2020 10:58:35	ACV0PFEINFP6000	Jesse	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
on Oct/21/2020 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:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		LePage (pfe.jlepage)	BPYV5B	
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**5.b**

Date	Location	User	Value	Reason
Oct-21-2020 10:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BMRTL B	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-21-2020 10:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BMRTL B	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-21-2020 10:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BMRTL C	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-21-2020 10:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BMRTL C	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levissc

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

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

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

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Oct-21-2020 10:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-21-2020 10:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-21-2020 10:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4027\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:** 10071280

**Generated By:** pfe.lewissc

**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

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Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levissc

**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

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Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071280

Generated By: pfe.lewissc

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

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**1. Category:**

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Muscle Soreness in arm of injection	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Jan/28/2021 20:00	Initial Entry

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

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO End Date Time:  Jan/30/2021 08:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae4027\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: 10071280

Generated By: pfe.lewissc

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

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (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
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae4027\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:** 10071280

**Generated By:** pfe.lewissc

**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)

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

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-17-2021 17:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levisse

**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

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**1. Category:**

Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> bilateral deep cervical swollen lymph nodes	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Feb/18/2021 08:00	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO End Date Time: Feb/25/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae4027\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: 10071280

Generated By: pfe.lewissc

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

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
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-08-2021 01:29:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Mar-05-2021 11:22:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-05-2021 11:22:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> RELATED	Initial Entry
Mar-05-2021 00:10:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajasheshkar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "Is this event related to study treatment" is missing. Kindly review and update.

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae4027\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:** 10071280

**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

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

Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 15:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-28-2021 13:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Dec/24/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25

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

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

Date	Location	User	Value	Reason
Jan-28-2021 13:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 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	Transcription Error
Jan-28-2021 13:50:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED - 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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-28-2021 13:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Jan/27/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-28-2021 13:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITI ONAL VACCINATION	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-28-2021 13:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Jan/28/2021	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, Locked, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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*I. Consent Was:*

Date	Location	User	Value	Reason
Jan-28-2021 13:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/28/2021	Initial Entry

090177e196ae4027\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, Locked, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

Date	Location	User	Value	Reason
Jan-28-2021 13:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Jan/28/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-28-2021 13:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-28-2021 13:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1007

Subject No: 10071280

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-28-2021 13:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-28-2021 13:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-28-2021 13:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Jan/28/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-28-2021 13:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-28-2021 13:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Jan-28-2021 13:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 <b>Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

			<b>Result::</b> NEGATIVE	
			<b>Not Done::</b>	

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-28-2021 13:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Jan-28-2021 13:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-28-2021 13:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae4027\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, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.levissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-28-2021 15:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-28-2021 13:52:02 (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.
Jan-28-2021 13:52:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection: Jan/28/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-28-2021 15:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BRB8ZX	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-28-2021 15:26:03	ACV0PFEINFP6000	Jesse	<b>Data Entry:</b>	Initial Entry

090177e196ae4027\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, Locked, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time  
(US & Canada)

LePage  
(pfe.jlepage)

BRB8ZX

**5.b**

Date	Location	User	Value	Reason
Jan-28-2021 15:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BNWMW6	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-28-2021 15:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BNWMW6	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-28-2021 15:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BNWMW8	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-28-2021 15:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BNWMW8	Initial Entry

090177e196ae4027\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, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.levissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-28-2021 15:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-28-2021 13:52:10 (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.
Jan-28-2021 13:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection: Jan/28/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-28-2021 15:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BRB900	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-28-2021 15:24:05	ACV0PFEINFP6000	Jesse	<b>Data Entry:</b>	Initial Entry

090177e196ae4027\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, Locked, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time  
(US & Canada)

LePage  
(pfe.jlepage)

BRB900

090177e196ae4027\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: 10071280

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Jan/28/2021 13:14	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

090177e196ae4027\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, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jan-28-2021 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-28-2021 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 13:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4027\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:** 10071280

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-17-2021 13:40:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Haley Muth (pfe.hmuth)	<b>Data Entry:</b> Feb/17/2021	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.levisse

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-17-2021 13:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-17-2021 13:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-17-2021 13:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Haley Muth (pfe.hmuth)	<b>Data Entry:</b> Feb/17/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Feb-17-2021 13:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Feb-17-2021 13:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Feb-17-2021 13:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 <b>Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001  
**Visit:** V102\_VAX4  
**Form Version:** 14-Jan-2021 02:21  
**Site No:** 1007  
**Subject No:** 10071280  
**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1007) Cincinnati Children's Hospital Medical Center  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:12

			<b>Result::</b> NEGATIVE <b>Not Done::</b>	
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-17-2021 13:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Feb-17-2021 13:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Haley Muth (pfe.hmuth)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Feb-17-2021 13:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Haley Muth (pfe.hmuth)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae4027\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, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071280

Subject Initials: ---

Generated By: pfe.lewissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-17-2021 13:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-17-2021 13:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-18-2021 10:17:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 08:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-17-2021 13:41:07 (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-17-2021 13:41:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Haley Muth (pfe hmuth)	<b>Data Entry:</b> YES Date of Collection:  Feb/17/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-18-2021 10:17:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	<b>Data Entry:</b> Sample ID: BR0ZR5	Initial Entry

090177e196ae4027\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, Locked, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-18-2021 10:17:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	<u><b>Data Entry:</b></u> BR0ZR5	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071280

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-17-2021 14:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Haley Muth (pfe.hmuth)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-17-2021 14:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-17-2021 14:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-17-2021 14:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Haley Muth (pfe.hmuth)	<b>Data Entry:</b> Feb/17/2021 13:35	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-17-2021 14:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-17-2021 14:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Haley Muth (pfe.hmuth)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

090177e196ae4027\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, Locked, Frozen, Verified

**Site No:** 1007

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

**Subject No:** 10071280

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

Date	Location	User	Value	Reason
Feb-17-2021 14:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-17-2021 14:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-17-2021 14:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-17-2021 14:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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-17-2021 14:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Haley Muth (pfe.hmuth)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4027\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: 10071280

Generated By: pfe.lewissc

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-21-2020 10:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-27-2020 10:33:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-27-2020 10:31:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Mar-05-2021 13:51:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Closed	Response satisfies query
Mar-04-2021 15:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	TrialMax DCF submitted for 25FEB2021 entry as participant did not have any protocol defined COVID symptoms
Mar-02-2021 22:35:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kirubakaran Kesavan Kendhapedi (pfe.kendak01)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 25FEB2021. But there is no COVID Illness visit reported in the database. Please clarify.
Oct-21-2020 10:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

090177e196ae4027\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:** 10071280

**Generated By:** pfe.lewissc

**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

Aug-27-2020 10:33:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/27/2020	Initial Entry
Aug-27-2020 10:31:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/27/2020	Initial Entry

090177e196ae4027\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071280

**Generated By:** pfe.levissc

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-28-2020 16:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Click Here to Enable	Initial Entry