

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**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:** 10071276

**Generated By:** pfe.levissc

**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/26/2020
----	--------------	----------------------------------------------------------

**Header Text:** c4591001  
**Visit:** COHORT\_SELECTION **Form:** DEMOGRAPHY  
**Form Version:** 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center  
**Subject No:** 10071276 **Subject Initials:** ---  
**Generated By:** pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10071276]
2.	Birth Date:	(b) (6)/1977
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**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/26/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**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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090177e196ae4021\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:** 10071276

**Generated By:** pfe.levissc

**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/26/2020
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:** 10071276

**Generated By:** pfe.lewissc

**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:	[Asthma]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vasectomy]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal allergy]
	Start Date:	UNK/UNK/1987
	Ongoing:	YES

090177e196ae4021\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:** 10071276

**Generated By:** pfe.lewissc

**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/26/2020
2.	Weight:	[91.4]
3.	Unit:	kg
4.	Height:	[187.0]
5.	Unit:	cm
6.	Body Mass Index:	[26.1]

**Vital Signs Details**

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

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<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> 10071276	<b>Generated Time (GMT):</b> 29-Mar-2021 04:12
<b>Generated By:</b> pfe.levissc	

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/26/2020
2.	Randomization Number:	[68489]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.levissc

**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/26/2020
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	[BP75HL]
5.b	Sample ID	[BP75HM]
5.c	Sample ID	[BP75HN]
5.d	Sample ID	[BPG0DV]
5.e	Sample ID	[BPG0DW]

090177e196ae4021\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:** 10071276

**Generated By:** pfe.lewissc

**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/26/2020
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	[BP75H2]
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090177e196ae4021\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:** 10071276

**Generated By:** pfe.lewissc

**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	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/26/2020 15:11
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

090177e196ae4021\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:** 10071276

**Generated By:** pfe.lewissc

**Form:** REACTOGENICITY DIARY

**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](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**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/17/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**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/17/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[37.2]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae4021\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:** 10071276

**Generated By:** pfe.lewissc

**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/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	[BPYTRY]
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090177e196ae4021\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:** 10071276

**Generated By:** pfe.lewissc

**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	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/17/2020 14:33
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

090177e196ae4021\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:** 10071276

**Generated By:** pfe.lewissc

**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	Oct/15/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**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: Oct/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYV2P]
5.b	Sample ID	[BMRTHG]
5.c	Sample ID	[BMRTHH]

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1007

**Subject No:** 10071276

**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	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

**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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090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1007

**Subject No:** 10071276

**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:** V5\_MONTH12\_L

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

**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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090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.levisc

**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:** V6\_MONTH24\_L

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

**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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090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** DATE OF VISIT - ILLNESS ONSET  
on Oct/07/2020

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/7/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Oct/07/2020

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

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

**Site No:** 1007

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

**Subject No:** 10071276

**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:	Oct/7/2020
2.	Date of First Symptom Started:	Oct/5/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Oct/10/2020

**Symptoms**

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

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Oct/07/2020

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

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

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Symptoms - Other**

5.

Symptoms - Other Text:

[ ]

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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.	Oct/10/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN  
on Oct/07/2020

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Oct/10/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[CLIA certified lab; PCR test]

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Oct/07/2020

**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:** 10071276

**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 unable]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Oct/07/2020

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Oct/07/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071276**Subject Initials:** ---**Generated By:** pfe.levissc**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
----	----------------------------------------------------------------------	----

**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:** 10071276

**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    **Form:** RESPIRATORY TREATMENT  
on Oct/07/2020

**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:** 10071276

**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?	

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Oct/07/2020

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

**Form Status:** Data Complete, Not Complete

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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?	YES Respiratory Illness Diagnosis: [seasonal allergies]  Date of Diagnosis: Oct/8/2020
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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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>

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE  
on Oct/07/2020

**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:** 10071276

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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>

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Oct/07/2020

**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:** 10071276

**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

090177e196ae4021\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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Oct/07/2020

**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:** 10071276

**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

090177e196ae4021\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:** 10071276

**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>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Oct/07/2020

**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:** 10071276

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Oct/07/2020

**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:** 10071276

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** OXYGENATION PARAMETERS  
on Oct/07/2020

**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:** 10071276

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Oct/07/2020

**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:** 10071276

**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?	

090177e196ae4021\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:** 10071276

**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>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING  
on Oct/07/2020

**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:** 10071276

**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 - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/25/2020

**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:** 10071276

**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/25/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/25/2020

**Form:** UNPLANNED VISIT

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/25/2020

**Form:** CONTACT OUTCOME - UNPLANNED

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Sep/25/2020  Contact Outcome: VISIT NOT ARRANGED, UNABLE TO ATTEND
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**Form:** DISPOSITION - TREATMENT

**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 - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/15/2020
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:** 10071276

**Generated By:** pfe.lewissc

**Form:** DISPOSITION - FOLLOW-UP

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	Dec/30/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	PROTOCOL DEVIATION
4.	Specify Status:	[Receipt of non-study COVID vaccine prior to study end]

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:** 10071276

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

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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	leukocytosis	Sep/24/2020 UNK:UNK	NO End Date Time:  Oct/19/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	thrombocytosis	Sep/24/2020 UNK:UNK	NO End Date Time:  Oct/26/2020 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	chronic myelogenous leukemia	Sep/24/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae4021\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:** 10071276

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, 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)	[leukocytosis]
4.	Start Date Time:	Sep/24/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/19/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Chronic myelogenous leukemia]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae4021\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:** 10071276

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[thrombocytosis]
4.	Start Date Time:	Sep/24/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/26/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Chronic myelogenous leukemia]

090177e196ae4021\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:** 10071276

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**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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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[chronic myelogenous leukemia]
4.	Start Date Time:	Sep/24/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? NO  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? YES  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae4021\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:** 10071276

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Genetic change in stem cells]
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?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020373397]

090177e196ae4021\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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:** 10071276

**Generated By:** pfe.levisse

**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	[ ]

090177e196ae4021\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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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.	1	VACCINATION S	NO	SARS-CoV-2 vaccination Pfizer	Dec/30/2020	<a href="#">Repeating Pages</a>

090177e196ae4021\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:** 10071276

**Generated By:** pfe.levisse

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

**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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[Form Audit Trail](#)

**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[SARS-CoV-2 vaccination Pfizer]
5.	Date:	Dec/30/2020

090177e196ae4021\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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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.	1	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Dasatinib	100	<a href="#">Repeating Pages</a>

090177e196ae4021\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:** 10071276

**Generated By:** pfe.levisse

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**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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**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY
3.	Concomitant Medications Pre-specified:	NO
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Dasatinib]
5.	Dose:	[100]
6.	Dose Unit:	mg
7.	Dose Frequency:	QD
8.	Route:	ORAL
9.	Start Date:	Oct/6/2020
10.	Ongoing?	YES

090177e196ae4021\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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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>

090177e196ae4021\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:** 10071276

**Generated By:** pfe.levisse

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1007

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

**Subject No:** 10071276

**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>

090177e196ae4021\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:** 10071276

**Generated By:** pfe.levisse

**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

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Vital Signs**

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

**Vital Signs Details**

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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?	

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001  
**Visit:** Unplanned Vaccination - Unscheduled      **Form:** CONTACT OUTCOME - MONTH 1  
**Form Version:** 10-Oct-2020 15:57      **Form Status:** Not Started  
**Site No:** 1007      **Site Name:** (1007) Cincinnati Children's Hospital Medical Center  
**Subject No:** 10071276      **Subject Initials:** ---  
**Generated By:** pfe.lewissc      **Generated Time (GMT):** 29-Mar-2021 04:12

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Informed Consent - Asymptomatic Surveillance**

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

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071276

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** 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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

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



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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 NOT willing to return for Vaccination 3 OR otherwise not eligible
----	-----------------------------------------------------------------------------------	----------------------------------------------------------------------------------

090177e196ae4021\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:** 10071276

**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 :	Dec/30/2020
2.	Primary Reason for Unblinding:	OTHER If other, specify: [Subject plans to receive non-study COVID vaccine]

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.levissc

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** 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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:** Subject Status - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Dec/30/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**Form:** CASEBOOK SIGNATURE FORM

**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](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
----	--------------------	--------------------------------------

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1007

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

**Subject No:** 10071276

**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
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 30-Jul-2020 21:29  
**Site No:** 1007  
**Subject No:** 10071276  
**Generated By:** pfe.levisse

**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-26-2020 15:17:38 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.levisse

**Form:** CASEBOOK SIGNATURE FORM - Signature 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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This form requires signing by a member of each of the following signature groups:

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
Laura Pace	N/A	Mar-11-2021 15:49:13 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Robert Frenck	Approved	Mar-08-2021 22:48:48 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	-------------------------------------------------------------	------	--------

**Affidavit:**

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

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

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

Laura Pace	N/A	Feb-21-2021 11:05:39 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Robert Frenck	Approved	Feb-07-2021 22:56:53 (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.

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Laura Pace	N/A	Jan-30-2021 09:38:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Robert Frenck	Approved	Oct-30-2020 12:00:10 (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	Oct-29-2020 11:46:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Robert Frenck	Approved	Oct-28-2020 18:25:42 (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	Oct-28-2020 16:56:36 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Robert Frenck	Approved	Oct-26-2020 17:54:33 (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	Oct-26-2020 10:46:59 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Robert Frenck	Approved	Oct-22-2020 08:35:55 (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.

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.levisse

**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

[Back to Form](#)

**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Aug-26-2020 15:16:51 (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-26-2020 15:16:51 (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:** 10071276

**Generated By:** pfe.levissc

**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

[Back to Form](#)

***1. Consent Was:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-26-2020 15:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b><u>Data Entry:</u></b> OBTAINED Date Written Consent Obtained  Aug/26/2020	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1007

Subject No: 10071276

Generated By: pfe.levissc

Form: DEMOGRAPHY - 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. Subject ID**

Date	Location	User	Value	Reason
Aug-26-2020 15:16:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10071276	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-26-2020 15:16:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1977	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-26-2020 15:17:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-26-2020 15:17:14 (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-26-2020 15:17:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae4021\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:** 10071276

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-26-2020 15:17:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

090177e196ae4021\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:** 10071276

**Generated By:** pfe.lewissc

**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

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

Date	Location	User	Value	Reason
Aug-26-2020 15:17:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-26-2020 15:17:54 (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-26-2020 15:17:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4021\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: 10071276

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

[Back to Form](#)

**1.a**

Date	Location	User	Value	Reason
Aug-26-2020 15:22:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 1 Medical History Term: Asthma Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 15:22:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 15:22:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Asthma	Initial Entry

**1.a Start Date:**

Date	Location	User	Value	Reason
Aug-26-2020 15:22:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Aug-26-2020 15:22:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

090177e196ae4021\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: 10071276

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

Date	Location	User	Value	Reason
Aug-26-2020 15:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 2 <b>Medical History Term:</b> Vasectomy <b>Start Date:</b> UNK/UNK/2016 <b>Ongoing:</b> NO End Date: UNK/UNK/2016	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 15:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 15:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Vasectomy	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-26-2020 15:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Aug-26-2020 15:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO End Date: UNK/UNK/2016	Initial Entry

090177e196ae4021\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: 10071276

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

*I.c*

Date	Location	User	Value	Reason
Oct-16-2020 20:05:02 (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> Seasonal allergy <b>Start Date:</b> UNK/UNK/1987 <b>Ongoing:</b> YES	Initial Entry

*I.c Line/MH Number:*

Date	Location	User	Value	Reason
Oct-16-2020 20:05:02 (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
Oct-16-2020 20:05:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Seasonal allergy	Initial Entry

*I.c Start Date:*

Date	Location	User	Value	Reason
Oct-16-2020 20:05:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> UNK/UNK/1987	Initial Entry

*I.c Ongoing:*

Date	Location	User	Value	Reason
Oct-16-2020 20:05:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4021\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: 10071276

Generated By: pfe.levissc

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-26-2020 15:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-26-2020 15:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 91.4	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-26-2020 15:19:13 (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-26-2020 15:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 187.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-26-2020 15:19:13 (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-26-2020 15:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 26.1	Initial Entry

090177e196ae4021\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: 10071276

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

7.a

Date	Location	User	Value	Reason
Aug-26-2020 15:19:13 (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 Locat</b> ORAL CAVI <b>ion::</b> TY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-26-2020 15:19:13 (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-26-2020 15:19:13 (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-26-2020 15:19:13 (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-26-2020 15:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae4021\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:** 10071276

**Generated By:** pfe.levissc

**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

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-26-2020 15:21:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-26-2020 15:21:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 68489	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071276

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Aug-26-2020 15:18:08 (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-26-2020 15:18:08 (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-26-2020 16:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-26-2020 15:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-26-2020 15:18:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection:  Aug/26/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-26-2020 16:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID: BP75HL</b>	Initial Entry

090177e196ae4021\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: 10071276

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 16:02:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BP75HL	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-26-2020 16:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BP75HM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 16:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BP75HM	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-26-2020 16:03:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BP75HN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 16:03:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BP75HN	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-26-2020 16:26:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BPG0DV	Initial Entry

090177e196ae4021\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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-26-2020 16:26:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BPG0DV	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-26-2020 16:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BPG0DW	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-26-2020 16:26:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BPG0DW	Initial Entry

090177e196ae4021\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: 10071276

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-26-2020 15:18:14 (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-26-2020 15:18:14 (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-26-2020 15:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-26-2020 15:18:14 (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-26-2020 15:18:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection:  Aug/26/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-26-2020 15:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID: BP75H2</b>	Initial Entry

090177e196ae4021\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:** 10071276

**Generated By:** pfe.levisse

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

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-26-2020 15:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BP75H2	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071276

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

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

Date	Location	User	Value	Reason
Aug-26-2020 15:56:02 (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-26-2020 15:56:02 (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-26-2020 15:56:02 (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-26-2020 15:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Aug/26/2020 15:11	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-26-2020 15:56:02 (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-26-2020 15:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae4021\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:** 10071276

**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

**7. Route:**

Date	Location	User	Value	Reason
Aug-26-2020 15:56:02 (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-26-2020 15:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION 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-26-2020 15:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4021\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:** 10071276

**Generated By:** pfe.lewissc

**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-26-2020 15:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIA RY 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:** 10071276

**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-15-2020 05:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Response satisfies query
Oct-14-2020 15:57:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	subject had visit on 07oct2020
Oct-13-2020 09:24:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonali shah (pfe.shahs132)	Query 1: Opened	As per Illness eduary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 08OCT2020. But there is no COVID Illness visit reported in the database.
Sep-17-2020 14:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/17/2020	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1007

Subject No: 10071276

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-17-2020 14:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/17/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-17-2020 14:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 37.2 <b>Temperature Unit:</b> C <b>Temperature Locat</b> ORAL CAVI <b>ion::</b> TY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-17-2020 14:20:43 (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-17-2020 14:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 37.2	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-17-2020 14:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071276

**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

Date	Location	User	Value	Reason
Sep-17-2020 14:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae4021\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:** 10071276**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-17-2020 14:21:05 (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 14:21:05 (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 15:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 14:21:05 (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 14:21:05 (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 15:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BPYTRY	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1007

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

**Subject No:** 10071276

**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>
Sep-17-2020 15:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BPYTRY	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071276

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

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

Date	Location	User	Value	Reason
Sep-17-2020 15:11:25 (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
Sep-17-2020 15:11:25 (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-17-2020 15:11:25 (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-17-2020 15:11:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/17/2020 14:33	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-17-2020 15:11:25 (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
Sep-17-2020 15:11:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae4021\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:** 10071276

**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

**7. Route:**

Date	Location	User	Value	Reason
Sep-17-2020 15:11:25 (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-17-2020 15:11:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION 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-17-2020 15:11:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4021\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:** 10071276

**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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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-15-2020 15:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071276

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-15-2020 15:26:34 (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
Oct-15-2020 15:26:34 (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
Oct-15-2020 15:26:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 15:26:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 15:26:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> YES Date of Collection:  Oct/15/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-15-2020 15:26:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID: BPYV2P</b>	Initial Entry

090177e196ae4021\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: 10071276

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:26:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BPYV2P	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-15-2020 15:26:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID: BMRTHG</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:26:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BMRTHG	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 15:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID: BMRTHH</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BMRTHH	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Oct/07/2020

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Oct-16-2020 01:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Closed	As per site confirmation - updated PD tracker
Oct-15-2020 08:31:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	correct neither nasal swab was done
Oct-15-2020 07:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Opened	PDQ : Details for either Nasal Swab Self or Nasal Swab expected to be completed. Please check and update else clarify.
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-14-2020 15:46:36 (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.
Oct-14-2020 15:46:36 (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.
Oct-14-2020 15:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Oct/07/2020

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-14-2020 15:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/07/2020

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

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

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

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Oct/5/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Oct-15-2020 19:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020 19:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Oct/10/2020	Transcription Error
Oct-15-2020 19:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Last Symptom Resolved Date is before the First Symptom Start Date. Please correct.
Oct-15-2020 19:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Sep/10/2020	New Information
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/07/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071276

Subject Initials: ---

Generated By: pfe.levisse

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

4.a

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (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> YES	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/07/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1007**Subject No:** 10071276**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**4.b Symptoms:**

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> YES	Initial Entry

**4.c Symptoms:**

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

**4.d**

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Oct/07/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071276**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

Oct-14-2020 15:51:42 (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
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**4.d Symptoms:**

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASE : D MUSCLE PAIN <b>Symptom</b> NO <b>Present:</b>	Initial Entry

**4.e Symptoms:**

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/07/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071276

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Symptoms: NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Symptoms NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Oct/07/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071276**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12**4.g Symptoms:**

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEW OR INCREASED SORE TH ROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Oct/07/2020

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

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

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

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**4.i Symptoms:**

Date	Location	User	Value	Reason
Oct-14-2020 15:51:42 (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
Oct-14-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Oct/07/2020

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

**Form Status:**

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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Date	Location	User	Value	Reason
Oct-15-2020 19:48:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/07/2020

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: 10071276

Subject Initials: ---

Generated By: pfe.levisse

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

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Oct-15-2020 19:48:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Oct/10/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Oct-15-2020 19:48:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Oct-15-2020 19:48:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Oct-15-2020 19:48:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Oct-15-2020 19:48:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Oct-15-2020 19:48:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> OTHER	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Oct/07/2020

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**7. Test Result:**

Date	Location	User	Value	Reason
Oct-15-2020 19:48:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEGATIVE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 19:48:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> CLIA certified lab; PCR test	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/07/2020

**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:** 10071276

**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
Oct-14-2020 15:53:41 (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-14-2020 15:53:41 (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
Oct-14-2020 15:53:41 (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-14-2020 15:53:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> subject unable	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Oct/07/2020

**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:** 10071276

**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-14-2020 15:53:57 (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-14-2020 15:53:57 (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
Oct-14-2020 15:53:57 (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-14-2020 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> subject unable	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/07/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071276

Subject Initials: ---

Generated By: pfe.lewissc

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

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**1.a**

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIA LIST <b>Occurrence of Visits or NO Contacts:</b>	Initial Entry

**1.a Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> SPECIALIST	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENC Y ROOM <b>Occurrence of Visits or NO Contacts:</b>	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/07/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071276**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (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

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

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

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

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/07/2020

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

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

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Oct-14-2020 15:47:01 (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
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***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> URGENT CARE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE C ONSULTATIO N <b>Occurrence of V isits or Contacts</b> : NO	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/07/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071276**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH R <b>Occurrence of Visits or C</b> NO <b>ontacts:</b>	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-14-2020 15:47:01 (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
Oct-14-2020 15:47:01 (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
Oct-14-2020 15:47:01 (UTC-05:00) Eastern	ACV0PFEINFP6000	Laura Pace	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Oct/07/2020

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

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

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)		(pfe.lpace)	
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090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Oct/07/2020

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

**Form Status:** Data Complete, Not Complete

**Site No:** 1007

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

**Subject No:** 10071276

**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
Oct-14-2020 15:54:14 (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
Mar-11-2021 15:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  seasonal allergies  Date of Diagnosis:  Oct/8/2020	New Information
Oct-14-2020 15:54:14 (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
Oct-14-2020 15:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Sep/25/2020

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

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-04-2020 19:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Closed	Response satisfies query
Oct-01-2020 16:10:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	subject had an SAE
Sep-28-2020 20:12:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Opened	ClinQuery: Please can you confirm why subject was called for UNPL visit? Subject is not part of reactogenicity subset of patients. If this pertains to an AE please update AE log else clarify. Thanks
Sep-25-2020 16:27:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/25/2020	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/25/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

**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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**I. Assessments**

Date	Location	User	Value	Reason
Sep-25-2020 16:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-25-2020 16:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Sep-25-2020 16:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/25/2020

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME - UNPLANNED - 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. Contact Type:**

Date	Location	User	Value	Reason
Sep-25-2020 16:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Sep-25-2020 16:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Contact:  Sep/25/2020  Contact Outcome:  VISIT NOT ARRANGED, UN ABLE TO ATTEND	Initial Entry

090177e196ae4021\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:** 10071276

**Generated By:** pfe.lewissc

**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-15-2020 15:27:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-15-2020 15:27:45 (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-15-2020 15:27:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)



Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1007

Subject No: 10071276

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP - 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 of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-30-2021 09:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-30-2021 09:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-22-2021 07:02:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Feb-21-2021 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-21-2021 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> PROTOCOL DEVIATION	Changed Information
Feb-15-2021 05:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	CLINQUERY: Please update status selection in field to match to PROTOCOL DEVIATION (will link to non-study covid-19 vaccine receipt prior to study end)
Feb-14-2021 18:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	protocol deviation completed

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP - 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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Feb-08-2021 02:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Opened	CLINQUERY: If non-study covid-19 vaccine was received prior to study end, please capture as PROTOCOL DEVIATION status
Feb-05-2021 06:03:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Candidate	CLINQUERY: If non-study covid-19 vaccine was received prior to study end, please capture as PROTOCOL DEVIATION status
Jan-30-2021 09:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO LONGER MEETS ELIGIBI LITY CRITERIA	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Feb-21-2021 11:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Receipt of non-study COVID vacci ne prior to study end	Changed Information
Jan-30-2021 09:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Exclusion 12; received a COVID-1 9 vaccine outside of the study.	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

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

**Form Status:**

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

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Sep-25-2020 16:35:56 (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:** 10071276

**Generated By:** pfe.levisse

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

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-25-2020 16:38:52 (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:** 10071276

**Generated By:** pfe.levisse

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

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071276

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, 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
Sep-25-2020 16:35:56 (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
Sep-25-2020 16:35:56 (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
Nov-05-2020 14:46:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Nov-04-2020 14:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	this was already done; see all AEs
Nov-04-2020 11:33:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Opened	CLINICAL Please clarify if a more specific diagnosis of CML has be reached; if so please update and report the specific diagnosis
Nov-04-2020 11:30:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Candidate	CLINICAL Please clarify if a more specific diagnosis of CML has be reached; if so please update and report the specific diagnosis

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.livissc

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

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

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

**Subject Initials:** ---

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

Sep-25-2020 16:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> leukocytosis	Initial Entry
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**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-25-2020 16:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/24/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 10:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO End Date Time: Oct/19/2020 UNK:UNK	New Information
Sep-25-2020 16:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-29-2020 14:59:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 3	Changed Information
Oct-27-2020 17:46:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Closed	Clin: Posted in error
Oct-27-2020 17:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Opened	Clin: Please clarify how this AE is life-threatening
Sep-25-2020 16:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 4	Initial Entry

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

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Oct-16-2020 05:29:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-15-2020 19:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE leukocytosis: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Oct-15-2020 19:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Changed Information
Sep-28-2020 03:28:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Deleted	Query can be addressed internally
Sep-25-2020 16:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE leukocytosis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-25-2020 16:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birt h defect?  NO  Did this serious event result in d eath?  NO	Initial Entry

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Generated By: pfe.levisse

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			<p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability /incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
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**8. Is this adverse event the result of a study Medication Error?**  
**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Sep-25-2020 16:35:56 (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
Oct-12-2020 09:18:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Chronic myelogenous leukemia	New Information
Sep-25-2020 16:35:56	ACV0PFEINFP6000	Laura	<b>Data Entry:</b>	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071276

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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)		Pace (pfe.lpace)	NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Probable lymphoproliferative disorder	
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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-25-2020 16:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 16:35:56 (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
Sep-25-2020 16:35:56 (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
Oct-26-2020 10:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-26-2020 10:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Oct-26-2020 10:46:59 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE leukocytosis: Response to "What

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**Subject No:** 10071276

**Generated By:** pfe.levisse

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

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Time (US & Canada)				was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-25-2020 16:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 16:35:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 05:29:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b>	downgraded to non serious in both database
Sep-28-2020 05:42:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020373397	Initial Entry

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**Header Text:** c4591001

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**1. Category:**

Date	Location	User	Value	Reason
Sep-25-2020 16:38:52 (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
Sep-25-2020 16:38:52 (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
Sep-25-2020 16:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> thrombocytosis	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-25-2020 16:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/24/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 16:56:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO End Date Time: Oct/26/2020 UNK:UNK	New Information
Sep-25-2020 16:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-29-2020 12:05:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 2: Closed	Response satisfies query
Oct-29-2020 11:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Oct-29-2020 11:46:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 3	Changed Information
Oct-29-2020 09:37:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 2: Opened	ClinQuery:thrombocytosis: this is listed as a grade 4 AE but is also listed as a not serious. Please review and update as appropriate. Thanks
Oct-27-2020 17:45:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Closed	Clin: Posted in error
Oct-27-2020 17:45:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Opened	Clin: Please clarify how this AE is life-threatening
Sep-25-2020 16:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-23-2020 11:12:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	updated per SAE report

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Oct-23-2020 11:07:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical - SAE report states "Thrombocytosis does still need to be reported as an SAE. It was inadvertently removed from the report sent to Pfizer on 09Oct2020." If statement is correct, please return this event to 'Serious = yes'.
Oct-16-2020 05:28:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-15-2020 19:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE thrombocytosis: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Oct-15-2020 19:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Changed Information
Sep-28-2020 03:28:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Deleted	Query can be addressed internally
Sep-25-2020 16:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE thrombocytosis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-25-2020 16:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or bir th defect?	Initial Entry

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			NO Did this serious event result in death?  NO Did this serious event require or prolong hospitalization?  NO Did this serious event result in persistent or significant disability/incapacity?  NO Is this serious event life threatening?  YES Other medically important serious event  NO	
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**8. Is this adverse event the result of a study Medication Error?**

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

Date	Location	User	Value	Reason
Sep-25-2020 16:38:52 (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
Oct-12-2020 09:43:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER	Changed Information

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			<i>If Other, specify:</i>  Chronic myelogenous leukemia	
Sep-25-2020 16:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Probable lymphoproliferative disorder	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-25-2020 16:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 16:38:52 (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
Sep-25-2020 16:38:52 (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
Oct-28-2020 16:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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Oct-28-2020 16:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Oct-28-2020 16:56:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE thrombocytosis: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-25-2020 16:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 16:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 05:28:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b>	downgraded to non serious in both database
Sep-28-2020 05:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020373397	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Oct-15-2020 19:59:41 (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
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> chronic myelogenous leukemia	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Sep/24/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Feb-01-2021 14:00:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Christian Mayfield (pfe.mayfc01)	Query 1: Closed	Response satisfies query
Feb-01-2021 12:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	Ae will not have an end date
Jan-30-2021 09:38:58 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is

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Time (US & Canada)				completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 4	Initial Entry

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

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Oct-29-2020 13:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Query closed; will follow for SAE update with the requested COVID test info
Oct-29-2020 11:29:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: Answered	will include in follow up SAE form
Oct-28-2020 23:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical - querying to have SAE report include any COVID test performed at Hosp. Orig response was "there was a covid test done and result was negative; testing was not performed due to the SAE", which is

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				unclear.
Oct-27-2020 16:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: Answered	can you please clarify what question you are referring to. I do not understand what you are asking
Oct-26-2020 16:33:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical The question only refers to (non-study) Covid tests in ER/Hospital. If NO hospital Covid test performed is known, please submit this on follow-up SAE form as pertinent information for this trial.
Oct-26-2020 09:57:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: Answered	there was a covid test done and result was negative; testing was not performed due to the SAE
Oct-23-2020 11:09:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020373397] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-16-2020 05:28:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE chronic myelogenous leukemia: Response to "Is the adverse event serious?" is

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				'Yes' but "Serious Adverse Event Number" is blank.
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

**8. Is this adverse event the result of a study Medication Error?***If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<p><b>Data Entry:</b></p> <p>NO</p>	Initial Entry

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

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Date	Location	User	Value	Reason
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s) , this event is due to:  OTHER  <i>If Other, specify:</i>  Genetic change in stem cells	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-15-2020 19:59:41 (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
Feb-16-2021 02:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	SDB update
Feb-11-2021 13:04:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Reissued:Cand idate	pending SDB update

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Time (US & Canada)				
Feb-10-2021 11:51:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	updated SAE report
Feb-10-2021 00:31:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020373397,outcome was updated to RECOVERING/RESOLVING on AE CRF while reported as Not Recovered/Not Resolved in Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-01-2021 12:51:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> RECOVERING/RESOL VING	Changed Information
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT RECOVERED/N OT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 19:59:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 05:28:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020373397	Initial Entry

090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1007

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

**Subject No:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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Date	Location	User	Value	Reason
Jan-31-2021 20:23:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	



Header Text: c4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071276

Subject Initials: ---

Generated By: pfe.levisse

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

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-31-2021 20:23:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Jan-31-2021 20:23:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Jan-31-2021 20:23:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Jan-31-2021 20:23:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> SARS-CoV-2 vaccination Pfizer	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Jan-31-2021 20:23:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

090177e196ae4021\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:** 10071276

**Generated By:** pfe.levissc

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - 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
Oct-16-2020 20:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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: 10071276

Subject Initials: ---

Generated By: pfe.levisse

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

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-16-2020 20:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-16-2020 20:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-16-2020 20:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Oct-16-2020 20:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Dasatinib	Initial Entry

**5. Dose:**

Date	Location	User	Value	Reason
Oct-16-2020 20:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 100	Initial Entry

**6. Dose Unit:**

Date	Location	User	Value	Reason
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090177e196ae4021\Final\Final On: 01-Apr-2021 05:31 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - 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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Oct-16-2020 20:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> mg	Initial Entry
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**7. Dose Frequency:**

Date	Location	User	Value	Reason
Oct-16-2020 20:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> QD	Initial Entry

**8. Route:**

Date	Location	User	Value	Reason
Oct-16-2020 20:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> ORAL	Initial Entry

**9. Start Date:**

Date	Location	User	Value	Reason
Oct-16-2020 20:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Oct/6/2020	Initial Entry

**10. Ongoing?**

Date	Location	User	Value	Reason
Oct-16-2020 20:08:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4021\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:** 10071276

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-30-2021 09:39:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Dec/23/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1007

**Subject No:** 10071276

**Generated By:** pfe.lewissc

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

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-30-2021 09:40:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071276

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-30-2021 09:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Mar-10-2021 02:51:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 2: Clo sed	Closed per site confirmation.
Mar-08-2021 21:23:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: An swere d	correct as entered
Mar-08-2021 05:21:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 2: Rei ssued: Opene d	IVRS Re-query 1: Thank you for response. Please confirm primary reason for unblinding recorded 'Other' is correct. Else, update as appropriate.
Mar-04-2021 21:49:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: An swere d	Changed Information
Mar-04-2021 21:49:06 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry</b> : OTH ER	Changed Information

090177e196ae4021\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:** 10071276

**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

Canada)			<i>If other, specify:</i>	
			Subject plans to receive non-study COVID vaccine	
Mar-04-2021 05:06:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_35
Mar-04-2021 02:55:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 2: Opened	IVRS Reconciliation: Other is selected as the primary reason for unblinding but matching blind break is not captured in IRT. Please correct primary reason in Inform or confirm as correct".
Mar-03-2021 23:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Reissued: Opened	DM : Primary Reason for Unblinding is recorded as OTHER. However, Other, specify is missing. Please review and

090177e196ae4021\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: 10071276

Generated By: pfe.levisse

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

				update. Else,clarify.
Mar-03-2021 14:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Changed Information
Mar-03-2021 14:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry</b> : OTH ER	Changed Information
Feb-22-2021 08:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7349520;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Jan-30-2021 09:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry</b> : ASSE SS EL IGIBI LITY FOR ADDI TION AL V ACCI NATI ON	Initial Entry

090177e196ae4021\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: 10071276

Generated By: pfe.levissc

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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**I. Subject Status**

Date	Location	User	Value	Reason
Feb-21-2021 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Changed Information
Jan-30-2021 09:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Oct-15-2020 15:27:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-26-2020 15:21:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-26-2020 15:17:54 (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
Feb-21-2021 11:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/30/2020	Changed Information
Jan-30-2021 09:38:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/30/2020	Initial Entry
Oct-15-2020 15:27:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/15/2020	Initial Entry
Aug-26-2020 15:21:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/26/2020	Initial Entry
Aug-26-2020 15:17:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/26/2020	Initial Entry

090177e196ae4021\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:** 10071276

**Generated By:** pfe.lewissc

**Form:** CASEBOOK SIGNATURE FORM - 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. Casebook Signature*

Date	Location	User	Value	Reason
Oct-21-2020 16:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Click Here to Enable	Initial Entry