

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

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: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/12/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10071306]
2.	Birth Date:	(b) (6)/1962
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae4022\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: 10071306

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Oct/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1007

Subject No: 10071306

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	Oct/12/2020
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: 10071306

Generated By: pfe.levissc

Form: GENERAL MEDICAL 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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Salpingo-oophorectomy unilateral]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	Jan/6/2020
	Ongoing:	YES

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Seasonal allergy]
	Start Date:	UNK/UNK/1992
	Ongoing:	YES

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

Form: HIV STATUS

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](#)

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

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:	Oct/12/2020
2.	Weight:	[93.3]
3.	Unit:	kg
4.	Height:	[170.2]
5.	Unit:	cm
6.	Body Mass Index:	[32.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.1]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Oct-2020 15:58**Site No:** 1007**Subject No:** 10071306**Generated By:** pfe.levissc**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

Form: RANDOMIZATION

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

1.	Randomization Date :	Oct/12/2020
2.	Randomization Number:	[268640]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

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	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/12/2020
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	[BPYTYV]
5.b	Sample ID	[BMPSMM]
5.c	Sample ID	[BMPSMN]

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**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:** 10071306**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?	YES Date of Collection: Oct/12/2020
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	[BPYTYN]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071306

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:	Oct/12/2020 15:31
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

090177e196ae4022\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: 10071306

Generated By: pfe.levissc

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

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	Nov/2/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

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:	Nov/2/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Oct-2020 15:58**Site No:** 1007**Subject No:** 10071306**Generated By:** pfe.levissc**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/2/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYV99]
-----	-----------	----------

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071306

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:	Nov/2/2020 13:44
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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10071306 **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	Nov/30/2020
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071306**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	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/30/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP90F8]
5.b	Sample ID	[BMRW8D]
5.c	Sample ID	[BMRW8J]

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071306

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:** 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:** 10071306**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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071306

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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

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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090177e196ae4022\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: 10071306

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

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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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

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	Jan/1/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Dec-2020 02:29

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jan/1/2021
2.	Date of First Symptom Started:	Dec/31/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/16/2021

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?	YES
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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?	YES
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.a	Symptoms - Other Text:	[chest tightness]
5.b	Symptoms - Other Text:	[fatigue]
5.c	Symptoms - Other Text:	[headache]

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 10071306

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.	Jan/3/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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[Form Comments](#)

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Microbiology Specimen

1.	Actual Date of Collection:	Jan/3/2021	Comments
2.	Specimen Type:	SWABBED MATERIAL	Comments
3.	Specimen Collection Location:	NASOPHARYNX	Comments
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Comments
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	Comments
6.	Trade Name:	OTHER	Comments
7.	Test Result:	POSITIVE	Comments
8.	Comments/Findings /Details:	[]	Comments
9.	Trade Name Other, Specify:	[CLIA certified lab]	Comments

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[RW86896]
-----	-----------	-----------

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071306**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HEALTH CARE UTILIZATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Health Care Utilization

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HEALTH CARE UTILIZATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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?	YES Has the subject been in intensive care due to potential COVID-19 illness? NO
----	--	--

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Jan/11/2021	NO Discharge Date: Jan/12/2021	Repeating Pages

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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[Form Audit Trail](#)

Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Jan/11/2021
4.	Ongoing?	NO Discharge Date: Jan/12/2021

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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?	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 06-Jul-2020 21:52

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: ILLNESS DETAILS

Form Status: Data Complete

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

Subject Initials: ---

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: [COVID-19] Date of Diagnosis: Jan/3/2021
3.	Toxicity Grade:	2

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 10071306

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.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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:	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	CLINICAL CHEMISTRY	TriHealth Laboratory 10500 Montgomery Road,Cincinnati,OH 45242	Jan/11/2021	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					329	C Reactive Protein_PX329	160	
					30	Alanine Aminotransferase_PX30	16	
					28	Aspartate Aminotransferase_PX28	[]	
					35	Alkaline Phosphatase_PX35	48	
					21	Bilirubin_PX21	.6	
					47	Blood Urea Nitrogen_PX47	14	
					48	Creatinine_PX48	.69	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 14-Jan-2021 02:30

Site No: 1007

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

Subject No: 10071306

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
2.	CLINICAL CHEMISTRY	TriHealth Laboratory 10500 Montgomery Road, Cincinnati, OH 45242	Jan/12/2021	BLO OD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					329	C Reactive Protein_PX329	[]	
					30	Alanine Aminotransferase_PX30	[]	
					28	Aspartate Aminotransferase_PX28	[]	
					35	Alkaline Phosphatase_PX35	[]	
					21	Bilirubin_PX21	[]	
					47	Blood Urea Nitrogen_PX47	19	
					48	Creatinine_PX48	.62	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[TriHealth Laboratory 10500 Montgomery Road,Cincinnati,OH 45242]
3.	Collection Date:	Jan/11/2021
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[160]
	Not Done:	
	LNMT	Low [0] High [4.9] Unit mg/L

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[16]
	Not Done:	
	LNMT	Low [10] High [60] Unit U/L
5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[48]
	Not Done:	
	LNMT	Low [35] High [135] Unit U/L
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[.6]
	Not Done:	
	LNMT	Low [0.0] High [1.2] Unit mg/dL

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[14]
	Not Done:	
	LNMT	Low [8] High [26] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[.69]
	Not Done:	
	LNMT	Low [.60] High [1.20] Unit mg/dL

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

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[Form Audit Trail](#)

Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[TriHealth Laboratory 10500 Montgomery Road, Cincinnati, OH 45242]
3.	Collection Date:	Jan/12/2021
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[19]
	Not Done:	
	LNMT	Low [8] High [26] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[.62]
	Not Done:	
	LNMT	Low [.6] High [1.2] Unit mg/dL

090177e196ae4022\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: 10-Oct-2020 16:02

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance																							
1.	HEMATOLOGY	TriHealth Laboratory 1 0500 Montgomery Road, Cincinnati, OH 45242	Jan/11/2021	BLOOD	<table border="1"> <thead> <tr> <th data-bbox="930 674 1079 825">Sponsor-Defined Identifier</th> <th data-bbox="1079 674 1214 825">Test:</th> <th data-bbox="1214 674 1292 825">Result:</th> </tr> </thead> <tbody> <tr> <td data-bbox="930 825 1079 966">1</td> <td data-bbox="1079 825 1214 966">Hemoglobin_PX1</td> <td data-bbox="1214 825 1292 966">12.4</td> </tr> <tr> <td data-bbox="930 966 1079 1106">2</td> <td data-bbox="1079 966 1214 1106">Hematocrit_PX2</td> <td data-bbox="1214 966 1292 1106">37.2</td> </tr> <tr> <td data-bbox="930 1106 1079 1247">3</td> <td data-bbox="1079 1106 1214 1247">Erythrocytes_PX3</td> <td data-bbox="1214 1106 1292 1247">4.31</td> </tr> <tr> <td data-bbox="930 1247 1079 1388">5</td> <td data-bbox="1079 1247 1214 1388">Platelets_PX5</td> <td data-bbox="1214 1247 1292 1388">319</td> </tr> <tr> <td data-bbox="930 1388 1079 1528">7</td> <td data-bbox="1079 1388 1214 1528">Leukocytes_PX7</td> <td data-bbox="1214 1388 1292 1528">5.3</td> </tr> <tr> <td data-bbox="930 1528 1079 1669">608</td> <td data-bbox="1079 1528 1214 1669">Neutrophils_PX608</td> <td data-bbox="1214 1528 1292 1669">81</td> </tr> <tr> <td data-bbox="930 1669 1079 1810">609</td> <td data-bbox="1079 1669 1214 1810">Eosinophils_PX609</td> <td data-bbox="1214 1669 1292 1810">0</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	1	Hemoglobin_PX1	12.4	2	Hematocrit_PX2	37.2	3	Erythrocytes_PX3	4.31	5	Platelets_PX5	319	7	Leukocytes_PX7	5.3	608	Neutrophils_PX608	81	609	Eosinophils_PX609	0		Repeating Pages
Sponsor-Defined Identifier	Test:	Result:																													
1	Hemoglobin_PX1	12.4																													
2	Hematocrit_PX2	37.2																													
3	Erythrocytes_PX3	4.31																													
5	Platelets_PX5	319																													
7	Leukocytes_PX7	5.3																													
608	Neutrophils_PX608	81																													
609	Eosinophils_PX609	0																													

090177e196ae4022\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: 10-Oct-2020 16:02

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
					612	Monocytes_PX612	8	
					610	Basophils_PX610	0	
					611	Lymphocytes_PX611	11	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[TriHealth Laboratory 10500 Montgomery Road, Cincinnati,OH 45242]
3.	Collection Date:	Jan/11/2021
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[12.4]
	Not Done:	
	LNMT	Low [12.0] High [15.2] Unit g/L

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[37.2]
	Not Done:	
	LNMT	Low [36] High [46] Unit %
5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[4.31]
	Not Done:	
	LNMT	Low [3.0] High [5.2] Unit 10 ³ /uL

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

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

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[319]
	Not Done:	
	LNMT	Low [140] High [375] Unit 10 ³ /uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[5.3]
	Not Done:	
	LNMT	Low [3.6] High [5.2] Unit g/dL

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[81]
	Not Done:	
	LNMT	Low [1.8] High [7.7] Unit 10 ³ /uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0]
	Not Done:	
	LNMT	Low [.03] High [.45] Unit 10 ³ /uL

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[8]
	Not Done:	
	LNMT	Low [.20] High [.90] Unit 10^3/uL
5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0]
	Not Done:	
	LNMT	Low [.00] High [.20] Unit 10^3/uL

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

5.j

Sponsor ID:	[611]
Test:	Lymphocytes_PX611
Result:	[11]
Not Done:	
LNMT	Low [1.00] High [4.00] Unit 10 ³ /uL

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

#	Date:	Vital Signs Details			Form Instance
1.	Jan/11/2021	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	134	70	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 14-Jan-2021 02:17

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

#	Date:	Vital Signs Details			Form Instance
2.	Jan/12/2021	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	127	68	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Vital Signs

1.	Date:	Jan/11/2021
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[134]
	Diastolic:	[70]
	Respiratory Rate in respirations/minute:	[24]
	Heart Rate in beats/minute:	[104]

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - COVID

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

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Vital Signs

1.	Date:	Jan/12/2021
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[127]
	Diastolic:	[68]
	Respiratory Rate in respirations/minute:	[20]
	Heart Rate in beats/minute:	[87]

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

#	Date:	Vital Signs Details		Form Instance
1.	Jan/11/2021	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	93.0	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 14-Jan-2021 02:17

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

#	Date:	Vital Signs Details		Form Instance
2.	Jan/12/2021	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	99.0	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Vital Signs

1.	Date:	Jan/11/2021
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Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[93.0]

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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Vital Signs

1.	Date:	Jan/12/2021
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[99.0]

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 10071306

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.				Repeating Pages

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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):	[]

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 10071306

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.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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?	

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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: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Jan/11/2021	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i> Patchy left bibasilar airspace disease consistent with pneumonia	Repeating Pages
2.	Jan/11/2021	CHEST	CT SCAN	NORMAL	Repeating Pages

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Imaging

1.	Date of Assessment:	Jan/11/2021
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Patchy left bibasilar airspace disease consistent with pneumonia]

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

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Imaging

1.	Date of Assessment:	Jan/11/2021
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	NORMAL

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

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Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19**Form Version:** 20-Feb-2021 02:17**Form Status:** Data Complete**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071306**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:	Feb/23/2021
2.	Date of First Symptom Started:	Feb/19/2021
3.	Symptoms Ongoing?	YES

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	YES
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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.	Symptoms - Other Text:	[]

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1007

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

Subject No: 10071306

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.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Microbiology Specimen

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071306**Generated By:** pfe.lewissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[participant did not have kit and was not interested in completing another nasal swab]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021**Form:** HEALTH CARE UTILIZATION**Form Version:** 20-Feb-2021 02:19**Form Status:** Data Complete**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071306**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:	YES Number of Visits or Contacts: [1]
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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
----	--	----

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL_2

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: HOSPITALIZATION DETAILS

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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Hospitalization Details

1.	Hospitalization Category:	
2.	Hospitalization Term:	
3.	Admission Date:	//
4.	Ongoing?	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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?	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

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?	NO
3.	Toxicity Grade:	2

Header Text: c4591001

Visit: POT_COVID_ILL 2

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: 10071306

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.					Repeating Pages

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1007

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

Subject No: 10071306

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:	Repeating Pages	
					[]		[]		
					[]		[]		
					[]		[]		
					[]		[]		
					[]		[]		
					[]		[]		
					[]		[]		

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
1.		[]			Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
[]		[]						
[]		[]						
[]		[]						
[]		[]						
[]		[]						
[]		[]						
[]		[]						
[]		[]						
[]		[]						
[]		[]						

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages
			[]	[]	

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1007

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

Subject No: 10071306

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	Repeating Pages
			[]	

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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.a	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1007

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

Subject No: 10071306

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.				Repeating Pages

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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 2

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: 10071306

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.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form Version: 06-Jul-2020 21:55

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

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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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?	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: IMAGING

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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/01/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

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	Feb/1/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/01/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071306**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRB91N]
5.b	Sample ID	[BNWMX0]
5.c	Sample ID	[BNWMX2]

Header Text: c4591001

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

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 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:** 10071306**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: 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: 10071306

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	left lower lobe pneumonia	Feb/23/2021 UNK:UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	sepsis	Feb/23/2021 UNK:UNK	YES	Repeating Pages

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[left lower lobe pneumonia]
4.	Start Date Time:	Feb/23/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [Legionella bacteria]</p>

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	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	[]

090177e196ae4022\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: 10071306

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[sepsis]
4.	Start Date Time:	Feb/23/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3

090177e196ae4022\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: 10071306

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	<p>NO</p>
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [Legionella bacteria]</p>

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	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	[]

090177e196ae4022\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: 10071306

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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Medication Error

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

090177e196ae4022\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: 10071306

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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.	Date:	//

090177e196ae4022\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: 10071306

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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: 10071306

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.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae4022\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: 10071306

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

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: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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Radiation Treatment

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

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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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

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: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
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: 10071306

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 - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

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

Subject No: 10071306 **Subject Initials:** ---

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

Unplanned Assessments

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

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: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

Vital Signs

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

Vital Signs Details

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071306**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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?	

090177e196ae4022\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: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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: 10071306

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 - **Form:** DATE OF VISIT
Unscheduled

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: 10071306

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: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

Informed Consent - Asymptomatic Surveillance

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

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:** 10071306**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:** 10071306**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: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/30/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

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: 10071306 **Subject Initials:** ---

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

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

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: 10071306 **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 willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

Disposition - Follow-Up

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

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: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/14/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

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: 10071306

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: V101_VAX3

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: 10071306

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: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

Informed Consent - Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	
----	--	--

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/30/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
Form	Oct-12-2020 14:22:04 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: HIV STATUS - 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	Oct-14-2020 13:43:17 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
Form	Oct-12-2020 15:38:55 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: HIV STATUS - 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
1	Oct-14-2020 13:43:17 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
1	Oct-12-2020 15:38:55 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
1	Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
2	Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
3	Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
4	Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
5	Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
6.a	Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
6.a	Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
6.a	Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
1	Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
2	Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
3	Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
4	Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
5	Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
6.a	Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

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Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
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Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
6.a	Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
6.a	Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
Form	Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
1	Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
1	Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
2	Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
2	Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

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Unscheduled Visit on Jan/01/2021

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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

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

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Item	Date	User	Comment
3	Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
3	Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

Header Text: c4591001

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Unscheduled Visit on Jan/01/2021

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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

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Subject Initials: ---

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

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Item	Date	User	Comment
4	Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
4	Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

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

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Item	Date	User	Comment
5	Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
5	Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

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

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Item	Date	User	Comment
6	Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
6	Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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Unscheduled Visit on Jan/01/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

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

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Item	Date	User	Comment
7	Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
7	Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

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

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Item	Date	User	Comment
8	Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
8	Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form Version: 06-Jul-2020 21:54

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Item	Date	User	Comment
9	Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
9	Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1007

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Item	Date	User	Comment
1	Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

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Item	Date	User	Comment
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3	Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

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

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Item	Date	User	Comment
4	Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

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Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

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Visit: POT_COVID_ILL 2 -
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Item	Date	User	Comment
6	Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

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7	Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

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Visit: POT_COVID_ILL 2 -
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Item	Date	User	Comment
8	Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
9	Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Done

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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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 10:46:24 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Robert Frenck	Approved	Mar-08-2021 23:04:08 (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	Feb-22-2021 22:05:29 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae4022\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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Affidavit:

N/A

Robert Frenck	Approved	Feb-15-2021 22:58:19 (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	Feb-12-2021 11:31:04 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Robert Frenck	Approved	Feb-07-2021 22:59:41 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae4022\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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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

Laura Pace	N/A	Jan-31-2021 19:48:28 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Robert Frenck	Approved	Jan-29-2021 22:59:15 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae4022\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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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

Laura Pace	N/A	Jan-26-2021 15:03:47 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Robert Frenck	Approved	Jan-23-2021 17:19:44 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae4022\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: 10071306

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - Signature
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Form Status: Data Complete, Verified

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

Subject Initials: ---

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

Affidavit:

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-12-2020 14:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 14:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - 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: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Consent Was:

Date	Location	User	Value	Reason
Oct-12-2020 14:21:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: OBTAINED Date Written Consent Obtained Oct/12/2020	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

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

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1. Subject ID

Date	Location	User	Value	Reason
Oct-12-2020 14:20:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10071306	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-12-2020 14:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1962	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-12-2020 14:21:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

Oct-12-2020 14:21:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT HISPANIC OR L ATINO(A) OR OF SP ANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Oct-12-2020 14:21:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: WHITE	Initial Entry

090177e196ae4022\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: 10071306

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
Oct-12-2020 14:21:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Oct/12/2020	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-12-2020 15:36:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Oct/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-12-2020 15:36:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-12-2020 15:36:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: COMPLETED	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Oct-12-2020 15:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical H Hysterecto istory Ter my m: Start Date UNK/UN : K/2003 Ongoing: NO End Date : UNK/U NK/200 3	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-12-2020 15:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Oct-12-2020 15:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Hysterectomy	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Oct-12-2020 15:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/2003	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-12-2020 15:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO End Date: UNK/UNK/2003	Initial Entry

1.b

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

<p>Oct-14-2020 08:54:27 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Laura Pace (pfe.lpace)</p>	<p>Data Entry: Line/M 2 H Num ber: Medica Salpingo-oo l Histor phorectomy y Term unilateral : Start D UNK/UNK/ ate: 2003 Ongoin NO g: End Date: UNK/UN K/2003</p>	<p>Changed Information</p>
<p>Oct-12-2020 15:40:18 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/MH 2 Number: Medical Salpingo-o History ophorecto Term: my Start Da UNK/UN te: K/2003 Ongoing NO : End Date : UNK/U NK/200 3</p>	<p>Initial Entry</p>

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-12-2020 15:40:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 19:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Closed	Response satisfies query
Oct-14-2020 08:54:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-14-2020 08:54:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Salpingo-oophorectomy unilateral	Changed Information
Oct-13-2020 21:57:24 (UTC-05:00)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Opened	ClinQuery: Please can you update to

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Eastern Time (US & Canada)				specify whether the Salpingo-oophorectomy is bilateral or unilateral? Thanks
Oct-12-2020 15:40:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Salpingo-oophorectomy	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Oct-12-2020 15:40:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/2003	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-12-2020 15:40:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO End Date: UNK/UNK/2003	Initial Entry

1.c

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Mar-12-2021 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Line/MH Number: 3 Medical History Term: Asthma Start Date: Jan/6/2020 Ongoing: YES	Changed Information
Oct-12-2020 15:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Asthma Start Date: Mar/UNK/2020 Ongoing: YES	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-12-2020 15:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 15:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Asthma	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Mar-12-2021 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/6/2020	Changed Information
Oct-12-2020 15:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Mar/UNK/2020	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-12-2020 15:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-12-2020 15:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 4 umber: Medical His Obesity tory Term: Start Date: UNK/U NK/200 3 Ongoing: YES	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-12-2020 15:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 15:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Obesity	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Oct-12-2020 15:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/2003	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-12-2020 15:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry
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I.e

Date	Location	User	Value	Reason
Oct-12-2020 15:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 5 umber: Medical His Seasonal tory Term: allergy Start Date: UNK/U NK/199 2 Ongoing: YES	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

1.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-12-2020 15:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 15:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Seasonal allergy	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Oct-12-2020 15:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/1992	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-12-2020 15:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: HIV STATUS - 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 - What is the subject HIV status?

Date	Location	User	Value	Reason
Oct-15-2020 20:45:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 1: Closed	Response satisfies query
Oct-14-2020 13:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-14-2020 13:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: The subject is NOT known to be HIV PO SITIVE	Initial Entry
Oct-14-2020 13:43:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry:	Initial Entry
Oct-13-2020 20:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 1: Opened	ClinQuery: Please confirm why the HIV status has been answered Not

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: HIV STATUS - 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

				applicable and not either a Yes or No?
Oct-12-2020 15:38:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Oct/12/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 93.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: kg	Initial Entry

4. Height:

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-12-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 170.2	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 32.2	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-12-2020 15:37:14 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Ide 1	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

Eastern Time (US & Canada)			ntifier:: Temperatur 36.1 e: Temperatur C e Unit: Temperatur ORAL e Location:: CAVIT Y	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 36.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-12-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: C	Initial Entry
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7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

			Not Done:: Not Applicable	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

6.a Not Done:

Date	Location	User	Value	Reason
Oct-12-2020 15:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-12-2020 15:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Oct/12/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-12-2020 15:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 268640	Initial Entry

090177e196ae4022\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: 10071306

Generated By: pfe.lewissc

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-12-2020 15:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-12-2020 15:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-12-2020 15:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020 15:36:24	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae4022\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:** 10071306**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-12-2020 15:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Oct/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 15:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BPYTY : V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 15:41:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BPYTYV	Initial Entry

5.b

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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-12-2020 15:41:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BMPSM D: M	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 15:41:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BMPSMM	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-12-2020 15:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BMPSM D: N	Initial Entry

090177e196ae4022\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: 10071306

Generated By: pfe.levissc

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 15:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BMPSMN	Initial Entry

090177e196ae4022\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: 10071306

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-12-2020 15:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-12-2020 15:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-12-2020 15:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020 15:36:32	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae4022\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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-12-2020 15:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Oct/12/2020	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 01:43:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Oct-13-2020 14:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-13-2020 14:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry:	Changed Information

090177e196ae4022\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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-13-2020 13:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 1: Opened	DM: A carriage is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Oct-12-2020 15:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry:	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 15:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BPYTY : N	Initial Entry

5.a Sample ID

090177e196ae4022\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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-12-2020 15:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BPYTYN	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-12-2020 16:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-12-2020 16:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-12-2020 16:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-12-2020 16:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Oct/12/2020 15:31	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-12-2020 16:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-12-2020 16:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-12-2020 16:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-12-2020 16:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 16:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-12-2020 16:07:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO - REACTOGENIC ITY E-DIARY NOT C OLLECTED FOR THI S SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071306

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
Nov-02-2020 14:45:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Nov/2/2020	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1007

Subject No: 10071306

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
Nov-02-2020 14:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Nov/2/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-02-2020 14:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier:: 1 Temperature: 36.6 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-02-2020 14:46:16 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Eastern Time (US & Canada)				
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2.a Temperature:

Date	Location	User	Value	Reason
Nov-02-2020 14:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 36.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-02-2020 14:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-02-2020 14:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

			Not Done:: Not Applicable	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

6.a Not Done:

Date	Location	User	Value	Reason
Nov-02-2020 14:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

090177e196ae4022\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: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-02-2020 14:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-02-2020 14:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-02-2020 14:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-02-2020 14:14:33	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae4022\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: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-02-2020 14:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: YES Date of Collection: Nov/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-02-2020 14:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BPYV9 : 9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-02-2020 14:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BPYV99	Initial Entry

090177e196ae4022\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: 10071306

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-02-2020 14:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-02-2020 14:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-02-2020 14:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - 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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-02-2020 14:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Nov/2/2020 13:44	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-02-2020 14:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-02-2020 14:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Nov-02-2020 14:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - 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: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-02-2020 14:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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
Nov-02-2020 14:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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: 10071306

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
Nov-30-2020 14:42:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Nov/30/2020	Initial Entry

090177e196ae4022\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: 10071306 **Subject Initials:** ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-30-2020 14:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-30-2020 14:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-30-2020 16:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-30-2020 14:42:41	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae4022\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:** 10071306**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-30-2020 14:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Nov/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-30-2020 16:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID: BP90F8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-30-2020 16:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BP90F8	Initial Entry

5.b

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: 10071306 **Subject Initials:** ---

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

Date	Location	User	Value	Reason
Nov-30-2020 16:37:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BMRW8 D: D	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-30-2020 16:37:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BMRW8D	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-30-2020 16:37:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BMRW8 D: J	Initial Entry

090177e196ae4022\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: 10071306 **Subject Initials:** ---

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

5.c Sample ID

Date	Location	User	Value	Reason
Nov-30-2020 16:37:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BMRW8J	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-06-2021 02:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 4: Closed	Response satisfies query
Jan-06-2021 00:03:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 3: Closed	Closed as data entered.
Jan-05-2021 16:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 4: Answered	completed
Jan-05-2021 16:38:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 3: Answered	completed
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

Form: DATE OF VISIT - ILLNESS ONSET - 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

(US & Canada)				
Jan-05-2021 06:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 4: Opened	DM: Kindly review and complete 'Health Care Utilization, Microbiology Specimen, Illness Details form' at this visit. Thank you.
Jan-05-2021 04:23:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Bembem Takhellambam (pfe.takheb)	Query 3: Opened	DM: Date of Visit is completed but Nasal Swab (SWAB PFE) CRF is not initiated. Please review and update the data as appropriate. Thanks
Jan-05-2021 01:19:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 2: Opened	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

				missing. Please review and update as appropriate.
Jan-04-2021 09:45:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-04-2021 09:45:09 (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.
Jan-04-2021 09:45:09 (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.

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-04-2021 09:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Jan/1/2021	Initial Entry
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3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-04-2021 09:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Dec-2020 02:29

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

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

Form Status: Data Complete

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 Assessment:

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/1/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Dec/31/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-26-2021 15:03:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO Date of Last Symptom Resolved: Jan/16/2021	New Information
Jan-05-2021	ACV0PFEINFP6000	Laura	Data Entry:	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

16:36:58
(UTC-05:00)
Eastern Time (US
& Canada)

Pace
(pfe.lpace)

YES

4.a

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptoms: FEVE R Symptom Pre NO sent:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Dec-2020 02:29

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

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

Form Status: Data Complete

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

Subject Initials: ---

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

4.b

Date	Location	User	Value	Reason
Jan-12-2021 15:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom Present: NEW OR INCREASED COUGH Symptom Present: YES	New Information
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom Present: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW OR INCREASE D COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-12-2021 15:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	New Information
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-12-2021 15:13:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symp NEW OR IN toms: CREASED S HORTNESS OF BREATH	New Information

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Dec-2020 02:29

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

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

Form Status: Data Complete

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

Subject Initials: ---

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

			Symp YES tom P resen t:	
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symp NEW OR IN toms: CREASED S HORTNESS OF BREATH Symp NO tom P resen t:	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW OR INCREASE D SHORTNESS OF B REATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-12-2021 15:13:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	New Information
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptoms: CHIL LS	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

			Symptom Pre YES sent:	
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4.d Symptoms:

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom Present: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Dec-2020 02:29

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

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

Form Status: Data Complete

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

Subject Initials: ---

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

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW OR INCREASE D MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW LOSS OF TAST E OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom NEW OR IN CREASED S ORE THROA T Symptom Present: YES	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW OR INCREASE D SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-12-2021 15:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptoms: DIARR HEA Symptom P YES resent:	New Information
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptoms: DIARR HEA	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)			Symptom P NO resent:	
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4.h Symptoms:

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-12-2021 15:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	New Information
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-05-2021	ACV0PFEINFP6000	Laura	Data Entry:	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

16:36:58 (UTC-05:00) Eastern Time (US & Canada)		Pace (pfe.lpace)	Symptoms: VOMIT ING Symptom P NO resent:	
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4.i Symptoms:

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-05-2021 16:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-05-2021 16:37:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptoms - chest tig Other: htness	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Dec-2020 02:29

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

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

Form Status: Data Complete

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

Subject Initials: ---

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

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-05-2021 16:37:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: chest tightness	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-12-2021 15:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptoms - Ot fatig her: ue	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-12-2021 15:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: fatigue	Initial Entry

5.c

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-12-2021 15:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptoms - heada Other: che	Initial Entry
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5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-12-2021 15:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: headache	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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Date	Location	User	Value	Reason
Jan-12-2021 15:07:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

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
Jan-12-2021 15:07:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/3/2021	Initial Entry
Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry:	Initial Entry
Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-12-2021 15:07:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SWABBED MATERI AL	Initial Entry
Jan-12-2021	ACV0PFEINFP6000	Laura	Data Entry:	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 06-Jul-2020 21:54

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

15:06:59 (UTC-05:00) Eastern Time (US & Canada)		Pace (pfe.lpace)		
Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-12-2021 15:07:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NASOPHARYNX	Initial Entry
Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry:	Initial Entry
Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jan-12-2021 15:07:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RE SP SYNDROME COR ONAVIRUS 2	Initial Entry
Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry:	Initial Entry
Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jan-12-2021 15:07:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGN OSTIC TEST	Initial Entry
Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry:	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry
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6. Trade Name:

Date	Location	User	Value	Reason
Jan-12-2021 15:07:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: OTHER	Initial Entry
Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry:	Initial Entry
Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-12-2021 15:07:45 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: POSITIVE	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Eastern Time (US & Canada)				
Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry:	Initial Entry
Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry:	Initial Entry
Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 06-Jul-2020 21:54

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jan-12-2021 15:07:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CLIA certified lab	Initial Entry
Jan-12-2021 15:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry:	Initial Entry
Jan-05-2021 16:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - 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. Data Origin

Date	Location	User	Value	Reason
Jan-04-2021 09:45:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-04-2021 09:45:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-04-2021 09:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-04-2021 09:45:28	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071306**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-04-2021 09:45:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: YES Date of Collection: Jan/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-04-2021 09:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I RW8689 D: 6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 09:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: RW86896	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-05-2021 16:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-05-2021 16:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-05-2021 16:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-05-2021 16:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: subject did not come in	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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1.a

Date	Location	User	Value	Reason
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Practitioner: SPECIALIST IALIS T Occurrence of NO Visits or Contacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

1.b

Date	Location	User	Value	Reason
Feb-24-2021 17:56:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Practitioner: EMERG ENCY ROOM Occurrence of Visits or Contacts: NO	Changed Information
Jan-12-2021 15:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Practitioner: EMERGE NCY RO OM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	New Information
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Practitioner: EMERG ENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

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
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EMERGENCY ROO M	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-24-2021 17:56:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Changed Information
Jan-12-2021 15:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	New Information
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

1.c

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Feb-24-2021 17:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of P PRIMAR ractitione Y CARE r: PHYSICI AN Occurren NO ce of Visit s or Cont acts:	Changed Information
Jan-12-2021 15:10:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of PRIMAR Practitio Y CARE P ner: HYSICIA N Occurre YES nce of Vi <i>Number</i> sits or C <i>of Visits</i> ontacts: <i>or Conta</i> <i>cts:</i> 2	New Information
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of P PRIMAR ractitione Y CARE r: PHYSICI AN	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

			Occurrence of Visits or Contacts:	
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: PRIMARY CARE PH YSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-24-2021 17:56:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Changed Information
Jan-12-2021 15:10:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES <i>Number of Visits or Contacts:</i> 2	New Information
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

1.d

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Feb-24-2021 17:57:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1	Changed Information
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-24-2021 17:57:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Changed Information
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Pr TELEPH actioner: ONE CO NSULTA	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)			TION	
			Occurrence of Visits or Contacts:	

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: TELEPHONE CON SULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Practitioner: OT HE R	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)			Occurrence of NO Visits or Conta cts:	
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 15:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Has the subject been in intensive care due to potential COVID- 19 illness?	New Information

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

			NO	
Jan-05-2021 16:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HOSPITALIZATION DETAILS - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Jan-12-2021 15:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: HOSPITALIZATION DETAILS - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Jan-12-2021 15:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION S TATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Jan-12-2021 15:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Jan-12-2021 15:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/11/2021	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: HOSPITALIZATION DETAILS - eCRF Audit
Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jan-18-2021 20:54:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO Discharge Date: Jan/12/2021	New Information
Jan-12-2021 15:11:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 06-Jul-2020 21:52

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Status: Data Complete

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 of Clinical Event:

Date	Location	User	Value	Reason
Jan-05-2021 16:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID- 19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 15:08:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES <i>Respiratory Illness</i> <i>Diagnosis:</i> COVID-19 Date of Diagnosis: Jan/3/2021	New Information
Jan-05-2021 16:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jan-12-2021 15:09:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 2	New Information
Jan-05-2021 16:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - Audit Trail

Form Version: 10-Oct-2020 15:58

Form Status:

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMIST RY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-21-2021 01:25:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Jan-20-2021 19:10:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-20-2021 19:10:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: TriHealth Laborato ry 10500 Montgo mery Road,Cincin nati,OH 45242	Changed Information
Jan-20-2021	ACV0PFEINFP6000	Swaranjali	Query 1: Opened	DM :A

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

11:52:17 (UTC-05:00) Eastern Time (US & Canada)		Subhash Pawar (pfe.pawars01)		carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: TriHealth Laborato ry 10500 Montgomer y Road, Cincinnati , OH 45242	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/11/2021	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Eastern Time (US
& Canada)

5.a

Date	Location	User	Value	Reason
Feb-01-2021 12:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor- 329 Defined Identifier: Test:: C Reactive Protein_ PX329 Result:: 160 Not Done :: Lab Normal Range: <i>Low</i> 0 <i>High</i> 4.9 <i>Unit</i> mg/L	Changed Information
Jan-31-2021 19:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor- 329 Defined Identifier:	New Information

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 -
 Unscheduled Visit on Jan/01/2021
Form Version: 10-Oct-2020 15:58
Site No: 1007
Subject No: 10071306
Generated By: pfe.levissc

Form: LOCAL LABORATORY DATA - REPEATING
 CHEMISTRY - eCRF Audit Trail History
Form Status: Data Complete
Site Name: (1007) Cincinnati Children's Hospital Medical
 Center
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:12

			Test:: C Reactiv e Protein_ PX329 Result:: 160 Not Done :: Lab Normal Range: <i>High</i> e: <5.0 <i>Unit</i> mg/L	
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- Defined Identifier: 329 Test:: C Reactiv e Protein_ PX329 Result:: 160 Not Done :: Lab Normal Range: <i>Low</i> e: <5.0 <i>Unit</i> mg/L	Initial Entry

5.a Sponsor ID:				
Date	Location	User	Value	Reason

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry
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5.a Test:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: C Reactive Protein_PX 329	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Feb-01-2021 12:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-31-2021 19:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

				confirm.
Jan-27-2021 23:26:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Reissued: Opened	DM : High range is missing in Lab Normal Range. Please review and update. Else, clarify.
Jan-27-2021 15:41:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Wendell (pfe.jwendell)	Query 1: Answered	Original value is correct
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 160	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

5.a LNMT

Date	Location	User	Value	Reason
Feb-01-2021 12:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 0 <i>High</i> 4.9 <i>Unit</i> mg/L	Changed Information
Jan-31-2021 19:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>High</i> <5.0 <i>Unit</i> mg/L	New Information
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> <5.0 <i>Unit</i> mg/L	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 30	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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)

Defined Identifier:

Test:: Alanine A
minotransfe
rase_PX30

Result:: 16

Not Done

::

Lab Normal Range: *Low*

Upper Limit: 10

Lower Limit:

High
60

Unit
U/L

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Alanine Aminotransfer ase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 16	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 10 <i>High</i> 60 <i>Unit</i> U/L	Initial Entry
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5.c

Date	Location	User	Value	Reason
Jan-18-2021 20:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 28 Defined I dentifier: Test:: Aspartate Aminotran sferase_PX 28 Result:: Not Done NOT DON :: E Lab Nor mal Ran ge:	Initial Entry
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor- Defined I dentifier:	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

& Canada)

Test:: Aspartate
Aminotran
sferase_PX
28

Result::
Not Done
::
Lab Nor
mal Ran
ge:

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 20:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Aspartate Aminotransf erase_PX28	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-18-2021 20:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 35 Defined Identifier: Test:: Alkaline P hosphatase _PX35 Result:: 48 Not Done: : Lab Normal Range: <i>Low</i> 35 <i>High</i> 135 <i>Unit</i> U/L	Initial Entry
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Alkaline Phosphatase_ PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 48	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 35 <i>High</i> 135 <i>Unit</i> U/L	Initial Entry
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5.e

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Def 21 ined Identifi er: Test:: Bilirubi n_PX21 Result:: .6 Not Done:: Lab Normal <i>Low</i> Range: 0.0 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: .6	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 0.0 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry
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5.f

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 47 Defined Identifier: Test:: Blood Urea Nitrogen _PX47 Result:: 14 Not Done: : Lab Normal Range: <i>Low</i> 8 <i>High</i> 26 <i>Unit</i> mg/dL	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Blood Urea Nitrogen_ PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 14	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
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Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 8 <i>High</i> 26 <i>Unit</i> mg/dL	Initial Entry
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5.g

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Def 48 ined Identifier: Test:: Creatinine_PX4 8 Result:: .69 Not Done:: Lab Normal Range: <i>Low</i> .60 <i>High</i> 1.20 <i>Unit</i> mg/dL	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: .69	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jan-18-2021 20:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> .60 <i>High</i> 1.20 <i>Unit</i> mg/dL	Initial Entry
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - 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
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMIST RY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: TriHealth Laboratory 10500 Montgomery R oad, Cincinnati, OH 45 242	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/12/2021	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry
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5.a

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-D 329 efined Ide ntifier: Test:: C Reactiv e Protein_ PX329 Result:: Not Done: NOT DO : NE Lab Norm al Range:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.a Test:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: C Reactive Protein_PX 329	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 30 Defined I dentifier: Test:: Alanine A minotransf erase_PX3 0 Result::	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

			Not Done NOT DON :: E Lab Normal Range:	
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Alanine Aminotransfer ase_PX30	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 28 Defined Identifier: Test:: Aspartate Aminotrans ferase_PX2 8 Result:: Not Done NOT DON :: E Lab Normal Range:	Initial Entry
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Aspartate Aminotransf erase_PX28	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-D 35 efined Identifier: Test:: Alkaline P hosphatas e_PX35 Result:: Not Done: NOT DO : Lab Normal Range:	Initial Entry
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Alkaline Phosphatase_ PX35	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Bilirubin_PX2 1 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Bilirubin_PX21	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

5.f

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 47 Defined Identifier: Test:: Blood Urea Nitrogen _PX47 Result:: 19 Not Done: : Lab Normal Range: <i>Low</i> 8 <i>High</i> 26 <i>Unit</i> mg/dL	Initial Entry
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Blood Urea Nitrogen_ PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 19	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 8 <i>High</i> 26 <i>Unit</i> mg/dL	Initial Entry
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5.g

Date	Location	User	Value	Reason
Feb-12-2021 11:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-D 48 efined Identifier: Test:: Creatinine_PX4 8 Result:: .62 Not Done:: Lab Normal Range: <i>Low</i> .6 <i>High</i> 1.2 <i>Unit</i> mg/dL	Transcription Error

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-D 48 efined Identifier: Test:: Creatinine_PX4 8 Result:: ,62 Not Done:: Lab Normal Range: <i>Low</i> .6 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:30

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Feb-12-2021 15:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mina Francisco (pfe.francm73)	Query 1: Closed	Response satisfies query
Feb-12-2021 11:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answer ed	Transcription Error

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Feb-12-2021 11:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: .62	Transcription Error
Feb-12-2021 09:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 1: Opened	Please update the comma in ",62" and replace with decimal point ".62" else clarify.
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ,62	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-31-2021 19:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> .6 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 16:02

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - 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
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-21-2021 04:32:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 1: Closed	Response satisfies query
Jan-20-2021 19:11:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-20-2021 19:11:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: TriHealth Laborato ry 10500 Montgom ery Road, Cincinna ti,OH 45242	Changed Information
Jan-20-2021	ACV0PFEINFP6000	Swaranjali	Query 1: Opened	DM :A

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 16:02

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

11:52:31 (UTC-05:00) Eastern Time (US & Canada)		Subhash Pawar (pfe.pawars01)		carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: TriHealth Laborato ry 10500 Montgomer y Road, Cincinnati, OH 45242	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/11/2021	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Eastern Time (US
& Canada)

5.a

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-De 1 fined Identi fier: Test:: Hemogl obin_PX 1 Result:: 12.4 Not Done:: Lab Normal <i>Low</i> Range: 12.0 <i>High</i> 15.2 <i>Unit</i> g/L	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)

5.a Test:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 12.4	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 12.0 <i>High</i> 15.2 <i>Unit</i>	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

			g/L	
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5.b

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Def 2 ined Identifier: Test:: Hematoc rit_PX2 Result:: 37.2 Not Done:: Lab Normal Low Range: 36 <i>High</i> 46 <i>Unit</i> %	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 16:02

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 37.2	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 36 <i>High</i> 46 <i>Unit</i> %	Initial Entry
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5.c

Date	Location	User	Value	Reason
Jan-31-2021 19:51:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-D 3 efined Identifier: Test:: Erythrocytes_PX 3 Result:: 4.31 Not Done:: Lab Normal Range: <i>Low</i> 3.0 <i>High</i> 5.2 <i>Unit</i> 10 ³ /u L	New Information

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 16:02

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 3 Test:: Erythrocytes_P X3 Result:: 4.31 Not Done: Lab Normal Range: <i>Low</i> 3.0 <i>High</i> 5.2	Initial Entry
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 16:02

Site No: 1007

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Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-31-2021 19:51:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit)

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form: LOCAL LABORATORY DATA - REPEATING
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Form Status: Data Complete, Queries

Site No: 1007

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Subject No: 10071306

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				is missing. Please correct or confirm.
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 4.31	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-31-2021 19:51:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 3.0 <i>High</i> 5.2 <i>Unit</i> 10 ³ /uL	New Information
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 3.0 <i>High</i> 5.2	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
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Form Status: Data Complete, Queries

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

Subject Initials: ---

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

Jan-31-2021 19:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-Def 5 ined Identifier: Test:: Platelet s_PX5 Result:: 319 Not Done:: Lab Normal Range: <i>Low</i> 140 <i>High</i> 375 <i>Unit</i> 10 ³ / uL	New Information
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Def 5 ined Identifier: Test:: Platelet s_PX5 Result:: 319 Not Done:: Lab Normal Range: <i>Low</i> 140 <i>High</i> 375	Initial Entry

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Header Text: c4591001

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Site No: 1007

Subject No: 10071306

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Form: LOCAL LABORATORY DATA - REPEATING
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Form Status: Data Complete, Queries

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Feb-01-2021 05:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 1: Closed	Response satisfies query
Jan-31-2021 19:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021**Form Version:** 10-Oct-2020 16:02**Site No:** 1007**Subject No:** 10071306**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Queries**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Jan-28-2021 10:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloi (pfe.moloim)	Query 1: Reissued: Opened	DM: Please note that the Unit is missing. Please review and correct.
Jan-27-2021 19:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	lab normal are present
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 319	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-31-2021 19:51:33 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 140	New Information

Header Text: c4591001

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

Subject No: 10071306

Subject Initials: ---

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

Eastern Time (US & Canada)			High 375 Unit 10^3/uL	
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Low 140 High 375	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Def 7 ined Identifier: Test:: Leukocytes_PX7 Result:: 5.3 Not Done::	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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			Lab Normal <i>Low</i>	
			Range: 3.6	
			<i>High</i>	
			5.2	
			<i>Unit</i>	
			g/dL	

Header Text: c4591001

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Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
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Form Status: Data Complete, Queries

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

Subject Initials: ---

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 5.3	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Mar-10-2021 22:19:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: Please the Low, High and the Unit entered on the CRF are not correct. Please review and update as appropriate
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 3.6 <i>High</i> 5.2 <i>Unit</i> g/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-31-2021 19:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-D 608 efined Ide ntifier: Test:: Neutrop hils_PX 608 Result:: 81 Not Done::	Changed Information

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

			Lab Norm <i>Low</i> al Range: 1.8 <i>High</i> 7.7 <i>Unit</i> 10^3/u L	
Jan-31-2021 19:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-D 608 efined Ide ntifier: Test:: Neutrop hils_PX6 08 Result:: 81 Not Done: : Lab Norm <i>Low</i> al Range: 1.8 <i>High</i> 7.7 <i>Unit</i> %	New Information
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-D 608 efined Ide	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

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Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
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Form Status: Data Complete, Queries

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

Subject Initials: ---

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

& Canada)

Identifier:

Test:: Neutrop
hils_PX6
08

Result:: 81

Not Done:

:

Lab Norm Unit

al Range: %

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 16:02

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-31-2021 19:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit)

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

				is missing. Please correct or confirm.
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 81	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-31-2021 19:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 1.8 <i>High</i> 7.7 <i>Unit</i> 10 ³ /uL	Changed Information
Jan-31-2021 19:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 1.8 <i>High</i> 7.7 <i>Unit</i> %	New Information

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Visit: POT_COVID_ILL 1 -
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Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Unit</i> %	Initial Entry
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5.g

Date	Location	User	Value	Reason
Jan-31-2021 19:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-D 609 efined Identifier: Test:: Eosinop hils_PX 609 Result:: 0 Not Done:: Lab Normal Range: <i>Low</i> .03 <i>High</i> .45 <i>Unit</i> 10 ³ /u L	Changed Information
Jan-31-2021 19:52:57 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-D 609 efined Identifier:	New Information

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1007

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& Canada)

Test:: Eosinop
hils_PX6
09

Result:: 0

Not Done:

:

Lab Norm *Low*

al Range: .03

High

.45

Unit

%

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

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5.g

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_PX60 9 Result:: 0 Not Done:: Lab Normal Range: <i>Unit</i> %	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Subject No: 10071306

Generated By: pfe.levisse

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-31-2021 19:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit)

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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Subject Initials: ---

Generated By: pfe.lewissc

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				is missing. Please correct or confirm.
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 0	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-31-2021 19:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> .03 <i>High</i> .45 <i>Unit</i> 10 ³ /uL	Changed Information
Jan-31-2021 19:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> .03 <i>High</i> .45 <i>Unit</i> %	New Information

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Generated By: pfe.lewissc

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

Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Unit</i> %	Initial Entry
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5.h

Date	Location	User	Value	Reason
Jan-31-2021 19:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-D 612 efined Ide ntifier: Test:: Monocy tes_PX6 12 Result:: 8 Not Done:: Lab Norm <i>Low</i> al Range: .20 <i>High</i> .90 <i>Unit</i> 10^3/u L	Changed Information
Jan-31-2021 19:53:22 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-D 612 efined Ide	New Information

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

& Canada)			Identifier: Test:: Monocytes_PX61 2 Result:: 8 Not Done: : Lab Normal Range: <i>Low</i> .20 <i>High</i> .90 <i>Unit</i> %	
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Monocytes_PX61 2 Result:: 8 Not Done: : Lab Normal Range: <i>Unit</i> %	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 16:02

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Jan-31-2021 19:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit)

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

				is missing. Please correct or confirm.
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 8	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Jan-31-2021 19:55:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> .20 <i>High</i> .90 <i>Unit</i> 10 ³ /uL	Changed Information
Jan-31-2021 19:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> .20 <i>High</i> .90 <i>Unit</i> %	New Information

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Unit</i> %	Initial Entry
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5.i

Date	Location	User	Value	Reason
Jan-31-2021 19:56:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-D 610 efined Identifier: Test:: Basophi ls_PX6 10 Result:: 0 Not Done:: Lab Normal Range: <i>Low</i> .00 <i>High</i> .20 <i>Unit</i> 10 ³ /u L	Changed Information
Jan-31-2021 19:53:46 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-D 610 efined Ide	New Information

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 16:02

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

& Canada)			ntifier: Test:: Basophi ls_PX61 0 Result:: 0 Not Done:: Lab Norm <i>Low</i> al Range: .00 <i>High</i> .20 <i>Unit</i> %	
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-D 610 efined Ide ntifier: Test:: Basophi ls_PX61 0 Result:: 0 Not Done:: Lab Norm <i>Unit</i> al Range: %	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 16:02

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-31-2021 19:53:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit)

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

				is missing. Please correct or confirm.
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 0	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-31-2021 19:56:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> .00 <i>High</i> .20 <i>Unit</i> 10 ³ /uL	Changed Information
Jan-31-2021 19:53:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> .00 <i>High</i> .20 <i>Unit</i> %	New Information

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Unit</i> %	Initial Entry
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5.j

Date	Location	User	Value	Reason
Jan-31-2021 19:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sponsor-D 611 efined Identifier: Test:: Lympho cytes_P X611 Result:: 11 Not Done: : Lab Norm <i>Low</i> al Range: 1.00 <i>High</i> 4.00 <i>Unit</i> 10^3/u L	New Information
Jan-18-2021 21:04:51 (UTC-05:00)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 611	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 16:02

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

Eastern Time (US & Canada)			Defined Identifier: Test:: Lymphocytes_PX 611 Result:: 11 Not Done: : Lab Normal Range: <i>Unit</i> % e:	
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 16:02

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Status: Data Complete, Queries

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

Subject Initials: ---

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-31-2021 19:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit)

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

				is missing. Please correct or confirm.
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 11	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Jan-31-2021 19:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Low</i> 1.00 <i>High</i> 4.00 <i>Unit</i> 10 ³ /uL	New Information
Jan-18-2021 21:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: <i>Unit</i> %	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - COVID - Audit Trail

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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Date	Location	User	Value	Reason
Jan-18-2021 21:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date:

Date	Location	User	Value	Reason
Jan-18-2021 21:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/11/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-18-2021 21:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier: 1 : Systolic:: 1 3 4 Diastolic:: 7 0 Respiratory Rate 2 in respirations/mi 4 nute: Heart Rate in bea 1 ts/minute: 0 4	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

Jan-18-2021 21:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry
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2.a Systolic:

Date	Location	User	Value	Reason
Jan-18-2021 21:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 134	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-18-2021 21:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 70	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-18-2021 21:05:45 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 24	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)				
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2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-18-2021 21:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 104	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - COVID - Audit Trail

Form Version: 14-Jan-2021 02:17

Form Status:

Site No: 1007

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

Subject No: 10071306

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 20:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date:

Date	Location	User	Value	Reason
Jan-31-2021 20:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/12/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-31-2021 20:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier: 1 : Systolic:: 1 2 7 Diastolic:: 6 8 Respiratory Rate 2 in respirations/mi 0 nute: Heart Rate in bea 8 ts/minute: 7	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail
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Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-31-2021 20:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry
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2.a Systolic:

Date	Location	User	Value	Reason
Jan-31-2021 20:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 127	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-31-2021 20:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 68	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-31-2021 20:02:08 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 20	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail
History

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-31-2021 20:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 87	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit
Trail

Form Version: 10-Oct-2020 16:04

Form Status:

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Jan-18-2021 21:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date:

Date	Location	User	Value	Reason
Jan-18-2021 21:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/11/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-18-2021 21:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier 1 r:: Oxygen Saturation: 93.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-18-2021 21:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 10-Oct-2020 16:04

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jan-18-2021 21:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 93.0	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit
Trail

Form Version: 14-Jan-2021 02:17

Form Status:

Site No: 1007

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

Subject No: 10071306

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 20:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date:

Date	Location	User	Value	Reason
Jan-31-2021 20:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/12/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-31-2021 20:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier 1 r:: Oxygen Saturation: 99. 0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-31-2021 20:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form Version: 14-Jan-2021 02:17

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF
Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Jan-31-2021 20:01:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 99.0	Initial Entry
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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Date	Location	User	Value	Reason
Jan-18-2021 21:06:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Feb-01-2021 12:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-18-2021 21:06:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/11/2021	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-18-2021 21:06:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-18-2021 21:06:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: X-RAY	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

Feb-02-2021 05:49:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloi (pfe.moloim)	Query 1: Closed	data entered correctly
Feb-01-2021 08:01:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	clarify where this is reported; there is not a field for that
Feb-01-2021 01:33:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Reissued :Opened	DM : Thanks for response. However, The response for "Assessment" is reported as 'Abnormal' however Clinical Significance is missing? Kindly review and update.
Jan-31-2021 19:48:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-31-2021 19:48:28	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ABNORMAL	New Information

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
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Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)			<i>If abnormal, specify findings:</i> Patchy left bib asilar airspace disease consist ent with pneu monia	
Jan-20-2021 01:07:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "Assessment" is reported as 'Abnormal' however Clinical Significance is missing? Kindly review and update.
Jan-18-2021 21:06:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ABNORMAL	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-01-2021 12:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/11/2021	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Feb-01-2021 12:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Feb-01-2021 12:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CT SCAN	Initial Entry

4. Assessment:

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/01/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Feb-01-2021 12:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: DATE OF VISIT - ILLNESS ONSET - 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 Visit

Date	Location	User	Value	Reason
Feb-24-2021 03:47:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Deleted	Query closed as per comments updated on Swab forms
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-23-2021 14:07:32 (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.
Feb-23-2021 14:07:32 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

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: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)				both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-23-2021 14:07:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Feb/23/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-23-2021 14:07:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form Version: 20-Feb-2021 02:17

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

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

Form Status: Data Complete

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 Assessment:

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Feb/23/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Feb/19/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

4.a

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Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: SIGNS AND SYMPTOMS OF POTENTIAL
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Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

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Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptoms: FEVE R Symptom Pre YES sent:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16	ACV0PFEINFP6000	Laura Pace	Data Entry: Sympto NEW OR IN	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.lpace)	ms: CREASED COUGH Symptom Present: YES	
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4.b Symptoms:

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW OR INCREASE D COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptoms: NEW OR INC REASED SH ORTNESS OF	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

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

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)			BREATH Symptom Present :	
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4.c Symptoms:

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW OR INCREASE D SHORTNESS OF B REATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptoms: CHIL LS	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

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

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Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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& Canada)

**Symptom Pre NO
sent:**

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sympt NEW OR IN oms: CREASED M USCLE PAIN Sympt NO om Pr esent:	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form Version: 20-Feb-2021 02:17

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

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

Form Status: Data Complete

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

Subject Initials: ---

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4.e Symptoms:

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW OR INCREASE D MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

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Form Status: Data Complete

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Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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4.f Symptoms:

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW LOSS OF TAST E OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom NEW OR IN CREASED S ORE THROA T Symptom Present: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form Version: 20-Feb-2021 02:17

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

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

Form Status: Data Complete

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

Subject Initials: ---

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

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW OR INCREASE D SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptoms: DIARR HEA Symptom P NO resent:	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

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Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

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

Form Status: Data Complete

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

Subject Initials: ---

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

4.h Symptoms:

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptoms: VOMIT ING Symptom P NO resent:	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
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Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

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

Form Status: Data Complete

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

Subject Initials: ---

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

4.i Symptoms:

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 14:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form Version: 06-Jul-2020 21:54

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: MICROBIOLOGY SPECIMEN - 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. Actual Date of Collection:

Date	Location	User	Value	Reason
Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Feb-23-2021 14:11:09 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Eastern Time (US
& Canada)

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Feb-23-2021 14:11:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Done	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - 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. Data Origin

Date	Location	User	Value	Reason
Feb-23-2021 14:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 14:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-23-2021 14:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-23-2021 14:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: participant did not have kit and was not interested in completing another nasal swab	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-23-2021 14:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 14:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-23-2021 14:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-23-2021 14:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: subject did not come in	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021**Form Version:** 20-Feb-2021 02:19**Site No:** 1007**Subject No:** 10071306**Generated By:** pfe.levissc**Form:** HEALTH CARE UTILIZATION - eCRF Audit
Trail History**Form Status:** Data Complete**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
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Practitioner: SPECIALIST IALIS T Occurrence of NO Visits or Contacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

1.b

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Pra EMERG ctitioner: ENCY R OOM Occurrence NO of Visits or Contacts:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EMERGENCY ROO M	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

1.c

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Pr PRIMAR actioner: Y CARE PHYSICI AN Occurren NO ce of Visit s or Conta cts:	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: PRIMARY CARE PH YSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

1.d

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Practice: URGENT CARE Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Number of Visits or Contacts: 1	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

I.e

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Pr TELEPH actitioner: ONE CO NSULTA TION Occurren NO ce of Visit s or Conta cts:	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: TELEPHONE CONS ULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

If

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Type of Practitioner: OT HE R Occurrence of Visits or Contacts: NO	Initial Entry

If Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: OTHER	Initial Entry

If Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

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

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form Version: 20-Feb-2021 02:19

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-24-2021 18:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-23-2021 14:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 08:31:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Opened	CLINQUERY: Is diagnosis made in relation to symptoms? Enter the diagnosis of the event if available even if not COVID-19 or Respiratory related. Record any diagnosis (where available) for the illness and in relation to reported

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Feb/23/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Queries

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

				symptoms.
Feb-23-2021 14:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-23-2021 14:09:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 2	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/01/2021

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
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 Visit

Date	Location	User	Value	Reason
Feb-01-2021 15:22:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Feb/1/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-01-2021 15:22:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: COVID_A1	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Feb-01-2021 15:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-01-2021 15:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-01-2021 15:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 15:22:46	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/01/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1007**Subject No:** 10071306**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-01-2021 15:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Feb/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-01-2021 15:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe.mmesseder)	Data Entry: Sample I BRB91 D: N	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 15:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe.mmesseder)	Data Entry: BRB91N	Initial Entry

5.b

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-01-2021 15:50:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe.mmesseder)	Data Entry: Sample I BNWM D: X0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 15:50:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe.mmesseder)	Data Entry: BNWMX0	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-01-2021 15:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe.mmesseder)	Data Entry: Sample I BNWM D: X2	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/01/2021

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071306

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - 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

5.c Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 15:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe.mmesseder)	Data Entry: BNWMX2	Initial Entry

090177e196ae4022\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: 10071306

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: left lower lobe pneumo nia	Initial Entry

4. Start Date Time:

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Feb/23/2021 UNK:UN K	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-12-2021 10:16:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE left lower lobe pneumonia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death?	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

			<p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>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
Mar-11-2021 10:46:24	ACV0PFEINFP6000	Laura Pace	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lpace

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

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

(pfe.lpace)

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT RELATED If Not Related to stud y treatment(s), this ev ent is due to: OTHER <i>If Other, specify:</i> Legionella bacter ia	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: RECOVERING/RESO LVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 10:46:24 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)				
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Category:

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: sepsis	Initial Entry

4. Start Date Time:

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Feb/23/2021 UNK:UN K	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-12-2021 10:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE sepsis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death?	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

			NO	
			Did this serious event require or prolong hospitalization?	
			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

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

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT RELATED If Not Related to stud y treatment(s), this ev ent is due to: OTHER <i>If Other, specify:</i> Legionella bacter ia	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-11-2021	ACV0PFEINFP6000	Laura	Data Entry:	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levisse

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

10:47:57 (UTC-05:00) Eastern Time (US & Canada)		Pace (pfe.lpace)	YES	
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: RECOVERING/RESO LVING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 10:47:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-30-2020 14:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Nov/30/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-30-2020 14:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-30-2020 14:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: COMPLETED	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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: 10071306 **Subject Initials:** ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-22-2021 22:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Dec/23/2020	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

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: 10071306 **Subject Initials:** ---

Generated By: pfe.lewissc **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
Feb-22-2021 22:05:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-22-2021 22:05:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Feb/14/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-22-2021 22:05:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Subject Status

Date	Location	User	Value	Reason
Nov-30-2020 14:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-12-2020 15:38:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-12-2020 15:36:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-30-2020 14:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/30/2020	Initial Entry
Oct-12-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

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

Subject No: 10071306

Subject Initials: ---

Generated By: pfe.levissc

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

15:38:21 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Oct/12/2020	
Oct-12-2020 15:36:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/12/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071306

Generated By: pfe.levissc

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
Jan-22-2021 07:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae4022\Final\Final On: 01-Apr-2021 05:31 (GMT)