

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 06-Jun-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

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	27 MAY 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 1 SENTINEL COHORTS

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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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jun/11/2020
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Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10071050]
2.	Birth Date:	(b) (6)/1982
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	

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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

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Date of Visit		
1.	Date of Visit	Jun/11/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

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[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00

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Form: INCLUSION/EXCLUSION CRITERIA

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

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1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00

1.d	Inclusion Number:	4
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

Exclusion Criteria

2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00

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Form: INCLUSION/EXCLUSION CRITERIA

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Form Status: Data Complete, Locked, Frozen, Verified

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2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00
2.e	Exclusion Number:	5
	Criterion Description:	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX05A00

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Form: INCLUSION/EXCLUSION CRITERIA

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Form Status: Data Complete, Locked, Frozen, Verified

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2.f	Exclusion Number:	6
	Criterion Description:	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX06A01
2.g	Exclusion Number:	7
	Criterion Description:	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX07A00
2.h	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00

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Form: INCLUSION/EXCLUSION CRITERIA

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2.i	Exclusion Number:	9
	Criterion Description:	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX09A00
2.j	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.k	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2.l	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00

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Subject Initials: ---

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2.m	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01
2.n	Exclusion Number:	14
	Criterion Description:	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX22A01
2.o	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01

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2.p	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.q	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2.r	Exclusion Number:	18
	Criterion Description:	Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX17A01

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2.s	Exclusion Number:	19
	Criterion Description:	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX18A01
2.t	Exclusion Number:	20
	Criterion Description:	Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX19A01
2.u	Exclusion Number:	21
	Criterion Description:	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX20A01

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Header Text: c4591001

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Form: INCLUSION/EXCLUSION CRITERIA

Form Version: 06-Jun-2020 00:48

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2.v	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

Header Text: c4591001

Visit: SCR

Form: DISPOSITION - SCREENING

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: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

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Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Jun/22/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL 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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

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Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Seasonal allergy]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Uterine leiomyoma]
	Start Date:	Sep/UNK/2019
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Anemia]
	Start Date:	Sep/UNK/2019
	Ongoing:	YES

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Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE

Form Version: 22-Apr-2020 21:04

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	1	GENERAL CONCOMITANT MEDICATIONS	NO	Ethinyl estradiol 20 microgram and norethindrone acetate 1 mg oral tablet	1/20	Repeating Pages
2.	2	GENERAL CONCOMITANT MEDICATIONS	NO	Chlorpheniramine maleate	4	Repeating Pages
3.	3	GENERAL CONCOMITANT MEDICATIONS	NO	Ferrous fumarate-containing product in oral dose form	1	Repeating Pages

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - 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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	GENERAL CONCOMITANT MEDICATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Ethinyl estradiol 20 microgram and norethindrone acetate 1 mg oral tablet]
5.	Dose:	[1/20]
6.	Dose Unit:	ug
7.	Dose Frequency:	QD
8.	Route:	ORAL
9.	Start Date:	UNK/UNK/2010

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Header Text: c4591001**Visit:** SCR**Form Version:** 22-Apr-2020 21:04**Site No:** 1007**Subject No:** 10071050**Generated By:** pfe.lewissc**Form:** CONCOMITANT MEDICATIONS - 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[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Concomitant Medications**

1.	What is the medication identifier?	[2]
2.	Category:	GENERAL CONCOMITANT MEDICATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Chlorpheniramine maleate]
5.	Dose:	[4]
6.	Dose Unit:	mg
7.	Dose Frequency:	PRN
8.	Route:	ORAL
9.	Start Date:	UNK/UNK/2016

Header Text: c4591001**Visit:** SCR**Form:** CONCOMITANT MEDICATIONS - BASELINE**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:** 10071050**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Concomitant Medications**

1.	What is the medication identifier?	[3]	
2.	Category:	GENERAL CONCOMITANT MEDICATIONS	
3.	Concomitant Medications Pre-specified:	NO	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Ferrous fumarate-containing product in oral dose form]	
5.	Dose:	[1]	
6.	Dose Unit:	Not Applicable	Comments
7.	Dose Frequency:	QD	
8.	Route:	ORAL	
9.	Start Date:	Feb/UNK/2020	

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

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Physical Examination

1.	Exam Date:	Jun/11/2020
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Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE
	Result:	NORMAL
2.b	Body System Examined:	SKIN
	Result:	NORMAL
2.c	Body System Examined:	HEAD
	Result:	NORMAL
2.d	Body System Examined:	EYES
	Result:	NORMAL
2.e	Body System Examined:	EARS
	Result:	NORMAL
2.f	Body System Examined:	NOSE
	Result:	NORMAL
2.g	Body System Examined:	THROAT
	Result:	NORMAL

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.h	Body System Examined:	HEART
	Result:	NORMAL
2.i	Body System Examined:	LUNGS
	Result:	NORMAL
2.j	Body System Examined:	ABDOMEN
	Result:	NORMAL
2.k	Body System Examined:	MUSCULOSKELETAL
	Result:	NORMAL
2.l	Body System Examined:	EXTREMITIES
	Result:	NORMAL
2.m	Body System Examined:	NEUROLOGICAL
	Result:	NORMAL
2.n	Body System Examined:	LYMPH NODES
	Result:	NORMAL

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: VITAL SIGNS - BASELINE

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jun/11/2020
2.	Weight:	[64.6]
3.	Unit:	kg
4.	Height:	[169.0]
5.	Unit:	cm
6.	Body Mass Index:	[22.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[37.3]
	Unit:	C
	Temperature Location:	ORAL CAVITY
	Systolic:	[117]
	Diastolic:	[89]
	BP Position:	SITTING
	Pulse:	[79]

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Header Text: c4591001

Visit: SCR

Form: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION

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: 10071050

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: Jun/11/2020
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	[BNBND2]
5.b	Sample ID	[BNBND3]
5.c	Sample ID	[BNY247]

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: MICROBIOLOGY SPECIMEN

Form Version: 22-Apr-2020 21:04

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

#	Date of Collection	Specimen Type	Assay Code and Description	Device Type	Result	Form Instance
1.	Jun/11/2020	BLOOD	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	NEGATIVE	Repeating Pages

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Header Text: c4591001

Visit: SCR

Form: MICROBIOLOGY SPECIMEN

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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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Microbiology Specimen

1.	Actual Date of Collection:	Jun/11/2020
2.	Specimen Type:	BLOOD
3.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
4.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
5.	Test Result:	NEGATIVE
6.	Comments/Findings /Details:	[]

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CENTRAL LAB SAMPLE COLLECTION - BASELINE

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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Central Lab Sample Collection

1.	Collection Date:	Jun/11/2020
2.	Specimen Type:	BLOOD

Lab Test

3.a	Lab Panel:	CLINICAL CHEMISTRY
	Lab Sub-Panel:	BLOOD CHEMISTRY
	Was the lab sub-panel collected?:	YES
3.b	Lab Panel:	CLINICAL CHEMISTRY
	Lab Sub-Panel:	VIROLOGY
	Was the lab sub-panel collected?:	YES
3.c	Lab Panel:	HEMATOLOGY
	Lab Sub-Panel:	DIFFERENTIAL
	Was the lab sub-panel collected?:	YES

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jun/11/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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: 10071050

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	Jun/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Not Applicable _____ //	Comments
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Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE	
	Result:	Not Applicable _____	Comments
2.b	Body System Examined:	SKIN	
	Result:	Not Applicable _____	Comments
2.c	Body System Examined:	HEAD	
	Result:	Not Applicable _____	Comments
2.d	Body System Examined:	EYES	
	Result:	Not Applicable _____	Comments
2.e	Body System Examined:	EARS	
	Result:	Not Applicable _____	Comments

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.f	Body System Examined:	NOSE	
	Result:	Not Applicable _____	Comments
2.g	Body System Examined:	THROAT	
	Result:	Not Applicable _____	Comments
2.h	Body System Examined:	HEART	
	Result:	Not Applicable _____	Comments
2.i	Body System Examined:	LUNGS	
	Result:	Not Applicable _____	Comments
2.j	Body System Examined:	ABDOMEN	
	Result:	Not Applicable _____	Comments
2.k	Body System Examined:	MUSCULOSKELETAL	
	Result:	Not Applicable _____	Comments
2.l	Body System Examined:	EXTREMITIES	
	Result:	Not Applicable _____	Comments

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.m	Body System Examined:	NEUROLOGICAL	
	Result:	Not Applicable _____	Comments
2.n	Body System Examined:	LYMPH NODES	
	Result:	Not Applicable _____	Comments

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: VITAL SIGNS

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jun/22/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY
	Systolic:	[119]
	Diastolic:	[72]
	BP Position:	SITTING
	Pulse:	[68]

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:47

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jun/22/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_S**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:** 10071050**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: Jun/22/2020
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	[BNBSW4]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: MICROBIOLOGY SPECIMEN

Form Version: 22-Apr-2020 21:05

Site No: 1007

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

Subject No: 10071050

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.	Jun/22/2020	SWABBED MATERIAL	NASAL CAVITY	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:05

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: MICROBIOLOGY SPECIMEN

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](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Jun/22/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASAL CAVITY
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	CEPHEID XPERT XPRESS SARS-COV-2 TEST
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071050

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 :	Jun/22/2020
2.	Randomization Number:	[2300]
3.	Randomization Group:	[Stage 1, Age 18 to 55, Medium dose level (30mcg), 21 Day (BNT162b2 or PBO)]

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:47

Site No: 1007

Subject No: 10071050

Generated By: pfe.levissc

Form: STRATIFICATION

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](#)

Stratification

1.	Select appropriate response - Randomization Stage	Stage 1
2.	Select appropriate response - Randomization Age Group	Age 18 to 55
3.	Select appropriate response - Randomization Dose	Medium dose level (30mcg)
4.	Select appropriate response - Randomization Dose Group	21 Day
5.	Select appropriate response - BNT Number	(BNT162b2 or PBO)

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Header Text: c4591001**Visit:** V1_DAY1_VAX1_S**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:** 10071050**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: Jun/22/2020
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	[BNBSWC]
5.b	Sample ID	[BNBSWD]
5.c	Sample ID	[BNBSWF]
5.d	Sample ID	[BNBSWG]
5.e	Sample ID	[BNBSWH]
5.f	Sample ID	[BNY28N]
5.g	Sample ID	[BNY28P]

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.h	Sample ID	[BNY28R]
5.i	Sample ID	[BNY28S]

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071050

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:	Jun/22/2020 11:17
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[0.5]
9.	Unit:	mL
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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

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: 10071050

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	Jun/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Not Applicable _____ //	Comments
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Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE	
	Result:	Not Applicable _____	Comments
2.b	Body System Examined:	SKIN	
	Result:	Not Applicable _____	Comments
2.c	Body System Examined:	HEAD	
	Result:	Not Applicable _____	Comments
2.d	Body System Examined:	EYES	
	Result:	Not Applicable _____	Comments
2.e	Body System Examined:	EARS	
	Result:	Not Applicable _____	Comments

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.f	Body System Examined:	NOSE	
	Result:	Not Applicable _____	Comments
2.g	Body System Examined:	THROAT	
	Result:	Not Applicable _____	Comments
2.h	Body System Examined:	HEART	
	Result:	Not Applicable _____	Comments
2.i	Body System Examined:	LUNGS	
	Result:	Not Applicable _____	Comments
2.j	Body System Examined:	ABDOMEN	
	Result:	Not Applicable _____	Comments
2.k	Body System Examined:	MUSCULOSKELETAL	
	Result:	Not Applicable _____	Comments
2.l	Body System Examined:	EXTREMITIES	
	Result:	Not Applicable _____	Comments

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.m	Body System Examined:	NEUROLOGICAL	
	Result:	Not Applicable _____	Comments
2.n	Body System Examined:	LYMPH NODES	
	Result:	Not Applicable _____	Comments

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: VITAL SIGNS

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jun/24/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	ORAL CAVITY
	Systolic:	[110]
	Diastolic:	[83]
	BP Position:	SITTING
	Pulse:	[90]

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 19-Jun-2020 21:47

Site No: 1007

Subject No: 10071050

Generated By: pfe.levissc

Form: CENTRAL LAB SAMPLE COLLECTION

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](#)

Central Lab Sample Collection

1.	Collection Date:	Jun/24/2020
2.	Specimen Type:	BLOOD

Lab Test

3.a	Lab Panel:	CLINICAL CHEMISTRY
	Lab Sub-Panel:	BLOOD CHEMISTRY
	Was the lab sub-panel collected?:	YES
3.b	Lab Panel:	HEMATOLOGY
	Lab Sub-Panel:	DIFFERENTIAL
	Was the lab sub-panel collected?:	YES

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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: 10071050

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	Jun/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.levisse

Form: PHYSICAL EXAMINATION

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](#)

Physical Examination

1.	Exam Date:	Not Applicable _____ //	Comments
----	------------	-------------------------------	--------------------------

Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE	
	Result:	Not Applicable _____	Comments
2.b	Body System Examined:	SKIN	
	Result:	Not Applicable _____	Comments
2.c	Body System Examined:	HEAD	
	Result:	Not Applicable _____	Comments
2.d	Body System Examined:	EYES	
	Result:	Not Applicable _____	Comments
2.e	Body System Examined:	EARS	
	Result:	Not Applicable _____	Comments

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.f	Body System Examined:	NOSE	
	Result:	Not Applicable _____	Comments
2.g	Body System Examined:	THROAT	
	Result:	Not Applicable _____	Comments
2.h	Body System Examined:	HEART	
	Result:	Not Applicable _____	Comments
2.i	Body System Examined:	LUNGS	
	Result:	Not Applicable _____	Comments
2.j	Body System Examined:	ABDOMEN	
	Result:	Not Applicable _____	Comments
2.k	Body System Examined:	MUSCULOSKELETAL	
	Result:	Not Applicable _____	Comments
2.l	Body System Examined:	EXTREMITIES	
	Result:	Not Applicable _____	Comments

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.m	Body System Examined:	NEUROLOGICAL	
	Result:	Not Applicable _____	Comments
2.n	Body System Examined:	LYMPH NODES	
	Result:	Not Applicable _____	Comments

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: VITAL SIGNS

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jun/29/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY
	Systolic:	[134]
	Diastolic:	[71]
	BP Position:	SITTING
	Pulse:	[80]

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 19-Jun-2020 21:47

Site No: 1007

Subject No: 10071050

Generated By: pfe.levissc

Form: CENTRAL LAB SAMPLE COLLECTION

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](#)

Central Lab Sample Collection

1.	Collection Date:	Jun/29/2020
2.	Specimen Type:	BLOOD

Lab Test

3.a	Lab Panel:	CLINICAL CHEMISTRY
	Lab Sub-Panel:	BLOOD CHEMISTRY
	Was the lab sub-panel collected?:	YES
3.b	Lab Panel:	HEMATOLOGY
	Lab Sub-Panel:	DIFFERENTIAL
	Was the lab sub-panel collected?:	YES

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V3_WEEK1_POSTVAX1_S**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:** 10071050**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: Jun/29/2020
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	[BNBT2P]
5.b	Sample ID	[BNBT2R]
5.c	Sample ID	[BNBT2S]
5.d	Sample ID	[BNBT2T]
5.e	Sample ID	[BNBT2V]
5.f	Sample ID	[BNY2FB]
5.g	Sample ID	[BNY2FC]

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.h	Sample ID	[BNY2FD]
5.i	Sample ID	[BNY2FF]

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10071050

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	Jul/13/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: PHYSICAL EXAMINATION

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Not Applicable _____ //	Comments
----	------------	-------------------------------	--------------------------

Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE	
	Result:	Not Applicable _____	Comments

2.b	Body System Examined:	SKIN	
	Result:	Not Applicable _____	Comments

2.c	Body System Examined:	HEAD	
	Result:	Not Applicable _____	Comments

2.d	Body System Examined:	EYES	
	Result:	Not Applicable _____	Comments

2.e	Body System Examined:	EARS	
	Result:	Not Applicable _____	Comments

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: PHYSICAL EXAMINATION

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.f	Body System Examined:	NOSE	
	Result:	Not Applicable _____	Comments
2.g	Body System Examined:	THROAT	
	Result:	Not Applicable _____	Comments
2.h	Body System Examined:	HEART	
	Result:	Not Applicable _____	Comments
2.i	Body System Examined:	LUNGS	
	Result:	Not Applicable _____	Comments
2.j	Body System Examined:	ABDOMEN	
	Result:	Not Applicable _____	Comments
2.k	Body System Examined:	MUSCULOSKELETAL	
	Result:	Not Applicable _____	Comments
2.l	Body System Examined:	EXTREMITIES	
	Result:	Not Applicable _____	Comments

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: PHYSICAL EXAMINATION

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.m	Body System Examined:	NEUROLOGICAL	
	Result:	Not Applicable _____	Comments
2.n	Body System Examined:	LYMPH NODES	
	Result:	Not Applicable _____	Comments

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VITAL SIGNS

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/13/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	ORAL CAVITY
	Systolic:	[119]
	Diastolic:	[77]
	BP Position:	SITTING
	Pulse:	[75]

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 19-Jun-2020 21:47

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jul/13/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10071050

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: Jul/13/2020
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	[BNBTD8]
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: MICROBIOLOGY SPECIMEN

Form Version: 22-Apr-2020 21:05

Site No: 1007

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

Subject No: 10071050

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.	Jul/13/2020	SWABBED MATERIAL	NASAL CAVITY	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: MICROBIOLOGY SPECIMEN

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Jul/13/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASAL CAVITY
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	CEPHEID XPERT XPRESS SARS-COV-2 TEST
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[]

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:52

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: CENTRAL LAB SAMPLE COLLECTION

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](#)

Central Lab Sample Collection

1.	Collection Date:	Jul/13/2020
2.	Specimen Type:	BLOOD

Lab Test

3.a	Lab Panel:	CLINICAL CHEMISTRY
	Lab Sub-Panel:	BLOOD CHEMISTRY
	Was the lab sub-panel collected?:	YES
3.b	Lab Panel:	HEMATOLOGY
	Lab Sub-Panel:	DIFFERENTIAL
	Was the lab sub-panel collected?:	YES

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V4_WEEK3_VAX2_S**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:** 10071050**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: Jul/13/2020
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	[BNBTFG]
5.b	Sample ID	[BNBTFH]
5.c	Sample ID	[BNBTFJ]
5.d	Sample ID	[BNBTFK]
5.e	Sample ID	[BNBTFL]
5.f	Sample ID	[BNY2PG]
5.g	Sample ID	[BNY2PH]

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.h	Sample ID	[BNY2PJ]
5.i	Sample ID	[BNY2PK]

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071050

Generated By: pfe.levissc

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:	Jul/13/2020 15:08
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[0.5]
9.	Unit:	mL
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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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: 10071050

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	Jul/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jul/16/2020
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Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE
	Result:	NOT DONE
2.b	Body System Examined:	SKIN
	Result:	NOT DONE
2.c	Body System Examined:	HEAD
	Result:	NOT DONE
2.d	Body System Examined:	EYES
	Result:	NOT DONE
2.e	Body System Examined:	EARS
	Result:	NOT DONE
2.f	Body System Examined:	NOSE
	Result:	NOT DONE
2.g	Body System Examined:	THROAT
	Result:	NOT DONE

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.h	Body System Examined:	HEART
	Result:	NOT DONE
2.i	Body System Examined:	LUNGS
	Result:	NOT DONE
2.j	Body System Examined:	ABDOMEN
	Result:	NOT DONE
2.k	Body System Examined:	MUSCULOSKELETAL
	Result:	NOT DONE
2.l	Body System Examined:	EXTREMITIES
	Result:	NOT DONE
2.m	Body System Examined:	NEUROLOGICAL
	Result:	NOT DONE
2.n	Body System Examined:	LYMPH NODES
	Result:	ABNORMAL If abnormal findings, specify: (If clinically significant, record on the Medical History or Adverse Event CRF as appropriate). [has 1x2 cm non-tender, mobile node in right axillae] Are there clinically significant findings? YES

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: VITAL SIGNS

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/16/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	ORAL CAVITY
	Systolic:	[124]
	Diastolic:	[81]
	BP Position:	SITTING
	Pulse:	[70]

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: CENTRAL LAB SAMPLE COLLECTION

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Central Lab Sample Collection

1.	Collection Date:	Jul/16/2020
2.	Specimen Type:	BLOOD

Lab Test

3.a	Lab Panel:	CLINICAL CHEMISTRY
	Lab Sub-Panel:	BLOOD CHEMISTRY
	Was the lab sub-panel collected?:	YES
3.b	Lab Panel:	HEMATOLOGY
	Lab Sub-Panel:	DIFFERENTIAL
	Was the lab sub-panel collected?:	YES

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V5_WEEK1_POSTVAX2_S**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:** 10071050**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: Jul/16/2020
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	[BP74PH]
5.b	Sample ID	[BP74PJ]
5.c	Sample ID	[BP74PK]
5.d	Sample ID	[BP74PL]
5.e	Sample ID	[BP74PM]
5.f	Sample ID	[BNY2VL]
5.g	Sample ID	[BNY2VM]

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.h	Sample ID	[BNY2VN]
5.i	Sample ID	[BNY2VP]

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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: 10071050

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	Jul/27/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jul/27/2020
----	------------	-------------

Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE
	Result:	NOT DONE
2.b	Body System Examined:	SKIN
	Result:	NOT DONE
2.c	Body System Examined:	HEAD
	Result:	NOT DONE
2.d	Body System Examined:	EYES
	Result:	NOT DONE
2.e	Body System Examined:	EARS
	Result:	NOT DONE
2.f	Body System Examined:	NOSE
	Result:	NOT DONE
2.g	Body System Examined:	THROAT
	Result:	NOT DONE

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.h	Body System Examined:	HEART
	Result:	NOT DONE
2.i	Body System Examined:	LUNGS
	Result:	NOT DONE
2.j	Body System Examined:	ABDOMEN
	Result:	NOT DONE
2.k	Body System Examined:	MUSCULOSKELETAL
	Result:	NOT DONE
2.l	Body System Examined:	EXTREMITIES
	Result:	NOT DONE
2.m	Body System Examined:	NEUROLOGICAL
	Result:	NOT DONE
2.n	Body System Examined:	LYMPH NODES
	Result:	NORMAL

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VITAL SIGNS

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/27/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	ORAL CAVITY
	Systolic:	[137]
	Diastolic:	[83]
	BP Position:	SITTING
	Pulse:	[78]

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V6_WEEK2_POSTVAX2_S**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:** 10071050**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: Jul/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP74YL]
5.b	Sample ID	[BP74YM]
5.c	Sample ID	[BP74YN]
5.d	Sample ID	[BP74YP]
5.e	Sample ID	[BP74YR]
5.f	Sample ID	[BNY31Y]
5.g	Sample ID	[BNY31Z]

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.h	Sample ID	[BNY320]
5.i	Sample ID	[BNY321]
5.j	Sample ID	[BNY322]
5.k	Sample ID	[BNY323]

Header Text: c4591001

Visit: V7_MONTH1_S

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: 10071050

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	Aug/10/2020
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V7_MONTH1_S**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:** 10071050**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: Aug/10/2020
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	[BM811Z]
5.b	Sample ID	[BM8120]
5.c	Sample ID	[BM8121]
5.d	Sample ID	[BM8122]
5.e	Sample ID	[BM8123]
5.f	Sample ID	[BPG03B]
5.g	Sample ID	[BPG03C]

Header Text: c4591001

Visit: V7_MONTH1_S

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: 10071050

Subject Initials: ---

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

5.h	Sample ID	[BPG03D]
5.i	Sample ID	[BPG03F]

Header Text: c4591001

Visit: V8_MONTH6_S

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: 10071050

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	Jan/4/2021
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V8_MONTH6_S**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:** 10071050**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: Jan/4/2021
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	[BR3YDD]
5.b	Sample ID	[BMNR6L]
5.c	Sample ID	[BMNR6S]

Header Text: c4591001

Visit: V9_MONTH12_S

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071050

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:** V9_MONTH12_S**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:** 10071050**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: V10_MONTH24_S

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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V10_MONTH24_S**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:** 10071050**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: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19**Form Version:** 20-Feb-2021 02:17**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071050**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**Signs and Symptoms**

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071050**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:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071050**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: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071050**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: 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: 10071050

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: 10071050 **Subject Initials:** ---

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

Unplanned Assessments

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Aug/10/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **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: 10071050

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:** 10071050**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Right axillary lymph node enlargement	Jul/15/2020 UNK:UNK	NO End Date Time: Jul/27/2020 UN K:UNK	Repeating Pages

090177e196ae402a\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: 10071050

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Right axillary lymph node enlargement]
4.	Start Date Time:	Jul/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jul/27/2020 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae402a\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: 10071050

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae402a\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, Locked, Frozen

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 22-Apr-2020 21:04

Site No: 1007

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

Subject No: 10071050

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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

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: 10071050

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	[]

090177e196ae402a\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: 10071050

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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 10071050

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.	<p>Medication:</p> <p>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).</p>	[]
5.	Date:	//

090177e196ae402a\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: 10071050

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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 10071050

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?	

090177e196ae402a\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: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 10071050

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?	

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1007

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

Subject No: 10071050

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: 10071050

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_BOOSTER_CONTACT
- 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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit:
UNPLANNED_BOOSTER_CONTACT
- Unscheduled

Form: BOOSTER DOSE TRIGGER FORM

Form Version: 20-Feb-2021 02:20

Form Status: Not Started

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

Booster Dose Trigger Form

1.	Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit?	
----	--	--

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: 10071050

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: 10071050

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:	

090177e196ae402a\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:** 10071050**Subject Initials:** ---**Generated By:** pfe.lewissc**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:** 10071050**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?	

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: 10071050

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: 10071050

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: 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: 10071050

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/28/2020
2.	Erroneous Visit	

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 10071050

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 and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	---

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: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/4/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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: 10071050

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:	[]

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 10071050

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	Aug/10/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

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

Subject No: 10071050

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, Signed, Verified

Site No: 1007

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

Subject No: 10071050

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

Name	Signature Meaning	Date	Type	Action
Robert Frenck	Approved	Mar-07-2021 21:07:19 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE - Comments

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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Item	Date	User	Comment
6	Jun-22-2020 11:49:04 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Item	Date	User	Comment
Form	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Item	Date	User	Comment
1	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Item	Date	User	Comment
2.a	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Item	Date	User	Comment
2.b	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

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Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

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

Subject Initials: ---

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Item	Date	User	Comment
2.c	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Item	Date	User	Comment
2.d	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

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Item	Date	User	Comment
2.e	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

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Item	Date	User	Comment
2.f	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Item	Date	User	Comment
2.g	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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Item	Date	User	Comment
2.h	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

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Item	Date	User	Comment
2.i	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Item	Date	User	Comment
2.j	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - 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
2.k	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - 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
2.1	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

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Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

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

Subject Initials: ---

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Item	Date	User	Comment
2.m	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - 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
2.n	Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

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Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - Comments

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

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Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - Comments

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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	Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

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Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - Comments

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2.a	Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - 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
2.b	Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

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Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - Comments

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2.c	Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - Comments

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2.d	Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

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Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - Comments

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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2.e	Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

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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
2.n	Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

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

Subject No: 10071050

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

Name	Signature Meaning	Date	Type	Action
Robert Frenck	Approved	Mar-07-2021 21:07:19 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Laura Pace	N/A	Feb-16-2021 16:06:27 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Robert Frenck	Approved	Jan-11-2021 15:47:30 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Affidavit:

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

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

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

Laura Pace	N/A	Jan-04-2021 10:20:41 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Robert Frenck	Approved	Aug-12-2020 14:52:55 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae402a\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: 10071050

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

Affidavit:

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

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

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

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

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
Jun-11-2020 15:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 27 MAY 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jun-11-2020 15:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: STAGE 1 SENTINEL COHORTS	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 10071050

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
Jun-11-2020 15:07:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: OBTAINED Date Written Consent Obtained Jun/11/2020	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:05

Site No: 1007

Subject No: 10071050

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
Jun-11-2020 15:06:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10071050	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: (b) (6)/1982	Changed Information
Jun-11-2020 15:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1982	Screening Log Entry

3. Sex:

Date	Location	User	Value	Reason
Jun-11-2020 15:07:28 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: FEMALE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Eastern Time (US & Canada)

4. Ethnicity:

Date	Location	User	Value	Reason
Jun-11-2020 15:07:28 (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

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

Date	Location	User	Value	Reason
Jun-11-2020 15:07:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ASIAN	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071050

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
Jun-11-2020 15:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/11/2020	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

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1.a

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<p>Data Entry:</p> <p>Incl 1 usio n N umb er:</p> <p>Crit Male or female erio participants bet n De ween the ages of scri 18 and 55 years, ptio inclusive, 65 an n: d 85 years, inclu sive, or 18 and 8 5 years, inclusiv e, at randomizati on (dependent u pon study stage)</p> <p>Crit YES erio n m et?:</p>	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Crit IN01A00 erion ID : (F or P fizer use only):	
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1.a Inclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

1.a Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

1.a Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

1.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Incl 2 usio n Nu mbe r:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

			<p>Crit Participants wh erio o are willing an n De d able to compl scrip y with all sched tion: uled visits, vacc ination plan, lab oratory tests, lif estyle considera tions, and other study procedure s</p> <p>Crit YES erio n me t?:</p> <p>Crit IN02A00 erio n ID : (Fo r Pfi zer u se on ly):</p>	
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

1.b Inclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

1.b Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

1.b Criterion ID: (For Pfizer use only)

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: IN02A00	Initial Entry

1.c

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Incl 3 usio n Nu mbe r: Crit Healthy particip erio ants who are det n De ermined by med scrip ical history, phy tion: sical examinatio n, and clinical j udgment of the i nvestigator to b e eligible for inc lusion in the stu dy Crit YES erio n me t?:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Crit IN03A00 erio n ID : (Fo r Pfi zer use only):	
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

I.c Inclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Healthy participants w ho are determined by medical history, physic al examination, and cli nical judgment of the i nvestigator to be eligib le for inclusion in the s tudy	Initial Entry

I.c Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

I.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Incl 4 usio n Nu mbe r: Crit Capable of givi erio ng personal sign n De ed informed con scrip sent, which incl tion: udes complianc e with the requi rements and rest rictions listed in the ICD and in t his protocol Crit YES erio n me t?:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

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Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

1.d Inclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

1.d Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

1.d Criterion ID: (For Pfizer use only)

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Excl 1 usio n N umb er: Crit Other medical o erio r psychiatric co n De ndition incl. rec scri ent (within past ptio year) or active s n: uicidal ideation/ behavior/lab ab normality that may increase th e risk of study p articipation Crit NO erio n m et?:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Crit EX01A00 erion ID : (For Pfizer use only):	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Other medical or psychiatric condition including recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.a Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Exclu 2 sion Num ber:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

			<p>Crite rion Known infecti on with human Descr immunodeficie ption ncy virus (HIV : , hepatitis C vi rus (HCV), or hepatitis B viru s (HBV)</p> <p>Crite rion NO met?:</p> <p>Crite rion I EX02A00 D: (F or Pfi zer us e only):</p>	
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX02A00	Initial Entry
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2.c

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Excl 3 usio n Nu mbe r: Crit History of sever erio e adverse reacti n De on associated w scrip ith a vaccine an tion: d/or severe aller gic reaction (eg, anaphylaxis) to any component of the study inte rvention(s) Crit NO erio n me t?:	Initial Entry

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Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Crit EX03A00 erio n ID : (Fo r Pfi zer u se on ly):	
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Header Text: c4591001

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Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.c Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.c Criterion ID: (For Pfizer use only)

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Site No: 1007

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Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Exclusion Number: Criterion Description: Receipt of medications intended to prevent COVID-19 Criterion met?: NO Criterion ID: (For Pfizer use only): EX04A00	Initial Entry

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Header Text: c4591001

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

Subject No: 10071050

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Generated By: pfe.lewissc

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2.d Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Receipt of medications intended to prevent C OVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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Header Text: c4591001

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX04A00	Initial Entry
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2.e

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Exclus 5 ion Nu mber: Criteria Stages 1 and on Des 2 only: Previo criptio us clinical or n: microbiologic al diagnosis o f COVID-19 Criteria NO on met ?: Criteria EX05A00 on ID: (For P fizer u se only):	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

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Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 5	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Stages 1 and 2 only: Pr evious clinical or micr obiological diagnosis o f COVID-19	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.e Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX05A00	Initial Entry
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2.f

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Exclu 6 sion Num ber: Crite Sentinel partici tion pants in Stage Descr 1 only: Individ ption uals at high ris : k for severe C OVID-19 (full details in proto col) Crite NO tion met?: Crite EX06A01 tion I D: (F or Pfi zer us e only):	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 6	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.f Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX06A01	Initial Entry
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2.g

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Excl 7 usio n N umb er: Crit Sentinel particip erio ants in Stage 1 o n De nly: Individuals scri currently workin ptio g in occupations n: with high risk of exposure to SA RS-CoV-2 (eg, h ealthcare worker , emergency res ponse personnel) Crit NO erio n m et?:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Crit EX07A00 erion ID : (F or P fizer use only):	
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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 7	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.g Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX07A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Excl 8 usio n Nu mbe r: Crite Immunocompro ri on mised individua Desc ls with known o ripti r suspected im on: munodeficiency , as determined by history and/ or laboratory/ph ysical examinat ion Crite NO ri on met? :	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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			Crite EX08A00 rion ID: (For Pfize r use only) :	
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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2.h Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 8	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.h Criterion ID: (For Pfizer use only)

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

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Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX08A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Exclusion Number: Criterion Description: Individuals with a history of an autoimmune disease or an active autoimmune disease requiring therapeutic intervention Criterion met?: NO	Initial Entry

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Header Text: c4591001

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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			Crite EX09A00 rion I D: (F or Pfi zer u se onl y):	
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Header Text: c4591001

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2.i Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 9	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.i Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX09A00	Initial Entry
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2.j

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Excl 10 usio n Nu mbe r: Crit Bleeding diathe erio sis or condition n De associated with scrip prolonged bleed tion: ing that would, in the opinion o f the investigato r, contraindicate intramuscular in jection Crit NO erio n me t?:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

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Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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			Crit EX10A00 erio n ID : (Fo r Pfi zer u se on ly):	
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Header Text: c4591001

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Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.j Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 10	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.j Criterion ID: (For Pfizer use only)

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Header Text: c4591001

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Subject Initials: ---

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Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX10A00	Initial Entry

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Header Text: c4591001

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2.k

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding Criterion Met?: NO Criterion ID: (For Pfizer use only): EX11A00	Initial Entry

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Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.k Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 11	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Women who are pregnant or breastfeeding	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.k Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX11A00	Initial Entry
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2.1

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Exclusion Number: Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: (For Pfizer use only): EX12A00	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 12	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: SCR

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Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX12A00	Initial Entry
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2.m

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Exclu 13 sion Num ber: Crite Subjects who rion receive immu Descr nosuppressive ption therapy, such : as cytotoxic a gents or syste mic corticoste roids Crite NO rion met?:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Crite EX13A01 rion I D: (F or Pfi zer us e only):	
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Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.m Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 13	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.m Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

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Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX13A01	Initial Entry
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2.n

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Exclus 14 ion N umber : Criterion Sentinel parti ion De cipants in Sta scripti ge 1 only: Re on: gular receipt of inhaled/ne bulized cortic osteroids Criterion NO ion m et?: Criterion EX22A01 ion ID : (For Pfizer use on ly):	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.n Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 14	Initial Entry

2.n Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids	Initial Entry

2.n Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.n Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX22A01	Initial Entry
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2.o

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Excl 15 usio n Nu mbe r: Crit Receipt of bloo erio d/plasma produ n De cts or immunog scrip lobulin, from 6 tion: 0 days before st udy interventio n administratio n or planned re ceipt throughou t the study Crit NO erio n me t?:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Crit EX14A01 erion ID : (For Pfizer usage only):	
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Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.o Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 15	Initial Entry

2.o Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.o Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.o Criterion ID: (For Pfizer use only)

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
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Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX14A01	Initial Entry

2.p

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Excl 16 usion Num ber: Crite Participation in rion other studies in Desc volving study i ripti ntervention wit on: hin 28 days pri or to study entr y and/or during study participa tion Crite NO rion met? :	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Crite EX15A01 rion ID: (For Pfize r use only) :	
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Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.p Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 16	Initial Entry

2.p Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.p Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.p Criterion ID: (For Pfizer use only)

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX15A01	Initial Entry

2.g

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Exclu 17 sion N umbe r: Criterion D Previous parti cipation in oth escrip er studies inv tion: olving study i ntervention co ntaining lipid nanoparticles Criterion NO ion m et?: Criterion EX16A01 ion ID : (For Pfizer use on ly):	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.q Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 17	Initial Entry

2.q Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanop articles	Initial Entry

2.q Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.q Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX16A01	Initial Entry
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2.r

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Excl 18 usion Num ber: Crite Sentinel partici rion pants in Stage Desc 1 only: Positiv ripti e serological te on: st for SARS-C oV-2 IgM and/ or IgG antibodi es at the screen ing visit Crite NO rion met? :	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

			Crite EX17A01 rion ID: (For Pfize r use only) :	
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Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.r Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 18	Initial Entry

2.r Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit	Initial Entry

2.r Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.r Criterion ID: (For Pfizer use only)

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

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Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX17A01	Initial Entry

2.s

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Exc 19 lusi on Nu mbe r: Crit Sentinel particip erio ants in Stage 1 o n D nly: Screening h escr ematology/bloo ipti d chemistry lab on: >=Grade 1 abno rmality. Except Bilirubin, other stable Grade1 a bnormalities ma y be considered eligible by Inves tigator	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			<p>Crit NO erion met?: Crit EX18A01 erion n I D: (For Pfizer use o nly) :</p>	
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.s Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 19	Initial Entry

2.s Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab \geq Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator	Initial Entry

2.s Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)				
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2.s Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX18A01	Initial Entry

2.t

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Excl 20 usio n N um ber:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

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Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			<p>Crit Sentinel particip erio ants in Stage 1 o n D nly: Positive tes escr t for HIV, hepati ipti tis B surface ant on: igen (HBsAg), h epatitis B core a ntibodies (HBc Abs), or hepatiti s C virus antibo dies (HCV Abs) at screening visi t</p> <p>Crit NO erio n m et?:</p> <p>Crit EX19A01 erio n I D: (For Pfz er u se o nly) :</p>	
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.t Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 20	Initial Entry

2.t Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit	Initial Entry

2.t Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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Generated By: pfe.levisse

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

2.t Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX19A01	Initial Entry

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

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2.u

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Excl 21 usion Num ber: Crite Sentinel partici rion pants in Stage Desc 1 only: SARS- ripti CoV-2 NAAT- on: positive nasal s wab within 24 hours before re ceipt of study i ntervention Crite NO rion met? : Crite EX20A01 rion ID: (For Pfize r use only) : 	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.u Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 21	Initial Entry

2.u Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention	Initial Entry

2.u Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.u Criterion ID: (For Pfizer use only)

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Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX20A01	Initial Entry

2.v

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Excl 22 usio n N umb er: Crit Investigator site erio staff or Pfizer e n De mployees direct scri ly involved in t ptio he conduct of th n: e study, site staf f otherwise sup ervised by the i nvestigator, and their respective family members Crit NO erio n m et?:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Crit EX21A01 erion ID : (F or P fizer use only):	
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Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.v Exclusion Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 22	Initial Entry

2.v Criterion Description:

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.v Criterion met?

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.v Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-22-2020 11:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EX21A01	Initial Entry

Header Text: c4591001

Visit: SCR

Form: DISPOSITION - SCREENING - 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: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jun-22-2020 11:37:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jun-22-2020 11:37:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jun-22-2020 11:37:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: COMPLETED	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** SCR**Form:** GENERAL MEDICAL HISTORY - 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:** 10071050**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Jun-22-2020 11:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: Medical History Term: Seasonal allergy Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Jun-22-2020 11:42:56 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Seasonal allergy	Initial Entry

Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - 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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Eastern Time (US & Canada)

1.a Start Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/2016	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Jun-22-2020 11:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Line/MH 2 Number: Medical History Term: Uterine leiomyoma	Changed Information

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Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - 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: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

			Start Date Sep/UN : K/2019 Ongoing: YES	
Jun-22-2020 11:44:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (auto calc)	Data Entry: Line/MH 2 Number: Medical H Uterine l istory Ter eiomyo m: ma Start Date Dec/UN : K/2019 Ongoing: YES	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - 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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:44:51 (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
Jun-22-2020 11:44:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Uterine leiomyoma	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sep/UNK/2019	Changed Information
Jun-22-2020 11:44:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Dec/UNK/2019	Initial Entry

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Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - 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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

I.b Ongoing:

Date	Location	User	Value	Reason
Jun-22-2020 11:44:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Jun-22-2020 11:45:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 3 umber: Medical His Anemia tory Term: Start Date: Sep/UN K/2019 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - 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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:45:14 (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
Jun-22-2020 11:45:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Anemia	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:45:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Sep/UNK/2019	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - 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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-22-2020 11:45:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE - Audit Trail

Form Version: 22-Apr-2020 21:04

Form Status:

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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Date	Location	User	Value	Reason
Jun-22-2020 11:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - BASELINE -
Audit Trail

Form Version: 22-Apr-2020 21:04

Form Status:

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
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Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Jun-22-2020 11:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE -
Audit Trail

Form Version: 22-Apr-2020 21:04

Form Status:

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Jun-22-2020 11:48:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

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Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-22-2020 11:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-22-2020 11:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: GENERAL CONCOM ITANT MEDICATION S	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jun-22-2020 11:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic

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Form: CONCOMITANT MEDICATIONS - BASELINE - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jun-22-2020 11:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Ethinyl estradiol 20 microgram and norethindrone acetate 1 mg oral tablet	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jun-22-2020 11:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1/20	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jun-22-2020 11:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ug	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Jun-22-2020 11:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: QD	Initial Entry
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8. Route:

Date	Location	User	Value	Reason
Jun-22-2020 11:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/2010	Initial Entry

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Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE - 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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-22-2020 11:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-22-2020 11:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: GENERAL CONCOM ITANT MEDICATION S	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jun-22-2020 11:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE - 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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Jun-22-2020 11:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Chlorpheniramine mal eate	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jun-22-2020 11:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 4	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jun-22-2020 11:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE - 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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Jun-22-2020 11:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: PRN	Initial Entry
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8. Route:

Date	Location	User	Value	Reason
Jun-22-2020 11:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: UNK/UNK/2016	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE - 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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-22-2020 11:48:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-22-2020 11:48:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: GENERAL CONCOM ITANT MEDICATION S	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jun-22-2020 11:48:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE - 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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Jun-22-2020 11:48:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Ferrous fumarate-containing product in oral dose form	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jun-22-2020 11:48:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jun-22-2020 11:49:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE - 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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Jun-22-2020 11:48:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: QD	Initial Entry
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8. Route:

Date	Location	User	Value	Reason
Jun-22-2020 11:48:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:48:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Feb/UNK/2020	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Exam Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/11/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body Sys GENERA tem Exa L APPEA mined: RANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: GENERAL APPEAR ANCE	Initial Entry

2.a Result:

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System SKIN Examined: Result: NOR MAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SKIN	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.c

Date	Location	User	Value	Reason
Jun-22-2020 11:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: HEA D Result: NOR MAL	Initial Entry
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: HE AD Result:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)

2.c Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEAD	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.d

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: EYES Result: NOR MAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EYES	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.e

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: EARS Result: NOR MAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EARS	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.f

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: NOSE Result: NOR MAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOSE	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.g

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: THRO AT Result: NOR MAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: THROAT	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.h

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: HEAR T Result: NOR MAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEART	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.i

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: LUN GS Result: NOR MAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.i Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: LUNGS	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.j

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: ABDO MEN Result: NORMAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.j Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ABDOMEN	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.k

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body Syst MUSCUL em Exami OSKELE ned: TAL Result: NORMA L	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.k Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: MUSCULOSKELETA L	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.l

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examine d: EXTREMITIES Result: NORMAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EXTREMITIES	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.m

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examine d: NEURO LOGICA L Result: NORMA L	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.m Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEUROLOGICAL	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

2.n

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examine d: LYMPH NODES Result: NORMAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: LYMPH NODES	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/11/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 64.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: kg	Initial Entry

4. Height:

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 169.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (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
Jun-22-2020 11:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22.6	Initial Entry

7.a

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (UTC-05:00)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Id 1	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** SCR**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Version:** 19-Jun-2020 21:48**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071050**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12Eastern Time (US
& Canada)**Identifier::****Temperature:** 37.3**Temperature Unit:****Temperature Unit:** C**Temperature Unit:****Temperature Location:** ORAL**Temperature Location:** CAVITY

Y

Systolic: 117**Diastolic:** 89**BP Position:** SITTING**BP Position:** G**Pulse:** 79**7.a Record Identifier:**

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (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
Jun-22-2020 11:40:54 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 37.3	Initial Entry

Header Text: c4591001

Visit: SCR

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)

7.a Unit:

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL CAVITY	Initial Entry

7.a Systolic:

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 117	Initial Entry

7.a Diastolic:

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 89	Initial Entry

7.a BP Position:

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SITTING	Initial Entry

7.a Pulse:

Date	Location	User	Value	Reason
Jun-22-2020 11:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 79	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION - 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: 10071050

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
Jun-11-2020 15:08:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

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

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-12-2020 12:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-11-2020 15:08:11	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** SCR**Form:** ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION - 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:** 10071050**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.
Jun-11-2020 15:08:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Jun/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-12-2020 12:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBND : 2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-12-2020 12:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBND2	Initial Entry

5.b

Header Text: c4591001

Visit: SCR

Form: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION - 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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-12-2020 12:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBND : 3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jun-12-2020 12:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBND3	Initial Entry

5.c

Date	Location	User	Value	Reason
Jun-12-2020 12:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY24 : 7	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION - 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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sample ID

Date	Location	User	Value	Reason
Jun-12-2020 12:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY247	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 22-Apr-2020 21:04

Form Status:

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Jun-11-2020 15:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: MICROBIOLOGY SPECIMEN - 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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jun-11-2020 15:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/11/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-11-2020 15:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: BLOOD	Initial Entry

3. Assay Code and Description:

Date	Location	User	Value	Reason
Jun-11-2020 15:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RES P SYNDROME CORO NAVIRUS 2	Initial Entry

4. Device Type:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: MICROBIOLOGY SPECIMEN - 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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-11-2020 15:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGN OSTIC TEST	Initial Entry
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5. Test Result:

Date	Location	User	Value	Reason
Jun-11-2020 15:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEGATIVE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CENTRAL LAB SAMPLE COLLECTION -
BASELINE - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Collection Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/11/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Category CLINICA for Lab T L CHEMI est: STRY Subcatego BLOOD ry for La CHEMIS b Test: TRY	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CENTRAL LAB SAMPLE COLLECTION -
BASELINE - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Lab Sub- Panel Collected: YES	
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3.a Lab Panel:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CLINICAL CHEMIST RY	Initial Entry

3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: BLOOD CHEMISTR Y	Initial Entry

3.a Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CENTRAL LAB SAMPLE COLLECTION -
BASELINE - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

3.b

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Category CLINICA for Lab T L CHEMI est: STRY Subcatego VIROLO ry for La GY b Test: Lab Sub- YES Panel Col lected:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CENTRAL LAB SAMPLE COLLECTION -
BASELINE - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

3.b Lab Panel:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CLINICAL CHEMIST RY	Initial Entry

3.b Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: VIROLOGY	Initial Entry

3.b Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

3.c

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CENTRAL LAB SAMPLE COLLECTION -
BASELINE - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

<p>Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Laura Pace (pfe.lpace)</p>	<p>Data Entry: Category fo HEMAT r Lab Test: OLOGY Subcategor DIFFER y for Lab T ENTIA est: L Lab Sub-Pa YES nel Collecte d:</p>	<p>Initial Entry</p>
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

Form: CENTRAL LAB SAMPLE COLLECTION -
BASELINE - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

3.c Lab Panel:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEMATOLOGY	Initial Entry

3.c Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: DIFFERENTIAL	Initial Entry

3.c Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

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

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/11/2020	Initial Entry

4. Laboratory Name and Address (Derived)

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

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

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-22-2020 11:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jun-22-2020 11:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: SCR

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

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Not Done ::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Choriogonadotropin B eta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEGATIVE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071050

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
Jun-22-2020 11:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/22/2020	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Exam Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.a Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.b

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: Not Applicable Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.c

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.c Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.d

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.e

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Result:	Initial Entry Not Applicable Not Applicable

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.f

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.g

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.h

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.i

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.i Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.j

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.j Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.k

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.k Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.l

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.m

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.m Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.n

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:48

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: VITAL SIGNS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jun-22-2020 11:50:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/22/2020	Transcription Error
Jun-22-2020 11:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital signs Date 15/Jun/2020 is not same as Date of Visit 22/Jun/2020. Please review and update as appropriate or clarify.
Jun-22-2020 11:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/15/2020	Initial Entry

2.a

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jun-22-2020 11:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier: 1 Temperature: 37.0 Temperature Unit: Temperature Location: ORAL CAVITY Systolic: 119 Diastolic: 72 BP Position: SITTING : G Pulse: 68	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:40	ACV0PFEINFP6000	Laura Pace	Data Entry: 37.0	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

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

(pfe.lpace)

2.a Unit:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:40 (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
Jun-22-2020 11:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL CAVITY	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 119	Initial Entry

2.a Diastolic:

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:48

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: VITAL SIGNS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jun-22-2020 11:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 72	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
Jun-22-2020 11:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 68	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Jun-22-2020 11:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-22-2020 11:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jun-22-2020 11:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/22/2020	Initial Entry

4. Laboratory Name and Address (Derived)

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-22-2020 11:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jun-22-2020 11:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jun-22-2020 11:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Not Done ::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jun-22-2020 11:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jun-22-2020 11:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Choriogonadotropin B eta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEGATIVE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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: 10071050

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
Jun-22-2020 11:52:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-22-2020 11:52:04 (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
Jun-22-2020 19:10:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-22-2020 11:52:04	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_S**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:** 10071050**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.
Jun-22-2020 11:52:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Jun/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-22-2020 19:10:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BNBSW D: 4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-22-2020 19:10:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBSW4	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:05

Site No: 1007

Subject No: 10071050

Generated By: pfe.levissc

Form: MICROBIOLOGY SPECIMEN - 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
Jun-22-2020 11:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

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
Jun-22-2020 11:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/22/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-22-2020 11:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SWABBED MATERIA L	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jun-22-2020 11:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL CAVITY	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-22-2020 11:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RES P SYNDROME CORO NAVIRUS 2	Initial Entry
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5. Device Type:

Date	Location	User	Value	Reason
Jun-22-2020 11:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jun-22-2020 11:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CEPHEID XPERT XP RESS SARS-COV-2 T EST	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jun-22-2020 11:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEGATIVE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)				
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071050

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
Jun-22-2020 11:53:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/22/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jun-22-2020 11:53:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 2300	Initial Entry

3. Randomization Group:

Date	Location	User	Value	Reason
Jun-22-2020 11:53:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Stage 1, Age 18 to 55, Medium dose level (30 mcg), 21 Day (BNT16 2b2 or PBO)	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:47

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: STRATIFICATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Randomization Stage

Date	Location	User	Value	Reason
Jun-22-2020 11:53:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Stage 1	Initial Entry

2. Select appropriate response - Randomization Age Group

Date	Location	User	Value	Reason
Jun-22-2020 11:53:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Age 18 to 55	Initial Entry

3. Select appropriate response - Randomization Dose

Date	Location	User	Value	Reason
Jun-22-2020 11:53:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Medium dose level (30 mcg)	Initial Entry

4. Select appropriate response - Randomization Dose Group

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:47

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: STRATIFICATION - 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

Jun-22-2020 11:53:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 21 Day	Initial Entry
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5. Select appropriate response - BNT Number

Date	Location	User	Value	Reason
Jun-22-2020 11:53:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: (BNT162b2 or PBO)	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071050

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
Jun-22-2020 11:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-22-2020 11:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-22-2020 19:13:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-22-2020 11:51:33	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_S**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:** 10071050**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.
Jun-22-2020 11:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Jun/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-22-2020 19:13:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BNBSW D: C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-22-2020 19:13:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBSWC	Initial Entry

5.b

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-22-2020 19:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BNBSW D: D	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jun-22-2020 19:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBSWD	Initial Entry

5.c

Date	Location	User	Value	Reason
Jun-22-2020 19:13:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BNBSW D: F	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sample ID

Date	Location	User	Value	Reason
Jun-22-2020 19:13:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBSWF	Initial Entry

5.d

Date	Location	User	Value	Reason
Jun-22-2020 19:13:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BNBSW D: G	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jun-22-2020 19:13:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBSWG	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-22-2020 19:13:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BNBSW D: H	Initial Entry
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5.e Sample ID

Date	Location	User	Value	Reason
Jun-22-2020 19:13:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBSWH	Initial Entry

5.f

Date	Location	User	Value	Reason
Jun-22-2020 19:13:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY28 : N	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.f Sample ID

Date	Location	User	Value	Reason
Jun-22-2020 19:13:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY28N	Initial Entry

5.g

Date	Location	User	Value	Reason
Jun-22-2020 19:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY28 : P	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jun-22-2020 19:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY28P	Initial Entry

5.h

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-22-2020 19:14:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY28 : R	Initial Entry
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5.h Sample ID

Date	Location	User	Value	Reason
Jun-22-2020 19:14:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY28R	Initial Entry

5.i

Date	Location	User	Value	Reason
Jun-22-2020 19:14:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY28 : S	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

5.i Sample ID

Date	Location	User	Value	Reason
Jun-22-2020 19:14:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY28S	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071050

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
Jun-22-2020 15:25:29 (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
Jun-22-2020 15:25:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jun-22-2020 15:25:29 (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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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-22-2020 15:25:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/22/2020 11:17	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jun-22-2020 15:25:29 (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
Jun-22-2020 15:25:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jun-22-2020 15:25:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

8. Actual Dose:

Date	Location	User	Value	Reason
Jun-22-2020 15:25:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 0.5	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jun-22-2020 15:25:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: mL	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jun-22-2020 15:25:29 (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
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071050

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

Jun-22-2020 15:25:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071050

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
Jun-24-2020 13:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/24/2020	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Exam Date:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Not Applicable Result: Not Applicable	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.a Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.b

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: Not Applicable Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.c

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.c Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.d

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.e

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Result:	Initial Entry Not Applicable Not Applicable

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.f

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Result:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.g

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.h

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.i

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Result:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.i Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.j

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

2.j Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.k

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.k Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.l

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.m

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.m Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.n

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 19-Jun-2020 21:48

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: VITAL SIGNS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/24/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-24-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier:: 1 Temperature: 36.5 Temperature Unit: Temperature Location: ORAL CAVITY Systolic:: 110 Diastolic:: 83 BP Position: SITTING : G Pulse:: 90	Initial Entry

2.a Record Identifier:

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jun-24-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 36.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:53 (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
Jun-24-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

& Canada)

2.a Systolic:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 110	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 83	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Jun-24-2020 13:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 90	Initial Entry
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Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Collection Date:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/24/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jun-24-2020 13:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Category CLINICA for Lab T L CHEMI est: STRY Subcatego BLOOD ry for La CHEMIS b Test: TRY	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Lab Sub- Panel Collected: YES	
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3.a Lab Panel:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: BLOOD CHEMISTRY	Initial Entry

3.a Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: CENTRAL LAB SAMPLE COLLECTION -
eCRF Audit Trail History

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

3.b

Date	Location	User	Value	Reason
Jun-24-2020 13:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Category fo HEMAT r Lab Test: OLOGY Subcategor DIFFER y for Lab T ENTIA est: L Lab Sub-Pa YES nel Collecte d:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: CENTRAL LAB SAMPLE COLLECTION -
eCRF Audit Trail History

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

3.b Lab Panel:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEMATOLOGY	Initial Entry

3.b Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: DIFFERENTIAL	Initial Entry

3.b Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jun-24-2020 13:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jun-29-2020 13:26:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/29/2020	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Exam Date:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Not Applicable Result: Not Applicable	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.a Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.b

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: Not Applicable Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.c

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Result:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.c Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.d

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.e

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.f

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Result:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.g

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.h

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.i

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Result:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.i Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.j

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.j Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.k

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.k Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.l

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Result:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.m

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.m Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.n

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 19-Jun-2020 21:48

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: VITAL SIGNS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jun-29-2020 13:27:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/29/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-29-2020 13:27:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier:: 1 Temperature: 37.0 Temperature Unit: C Temperature Location:: ORAL CAVITY Systolic:: 134 Diastolic:: 71 BP Position: SITTING Pulse:: 80	Initial Entry

2.a Record Identifier:

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jun-29-2020 13:27:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jun-29-2020 13:27:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 37.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jun-29-2020 13:27:41 (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
Jun-29-2020 13:27:41 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

& Canada)

2.a Systolic:

Date	Location	User	Value	Reason
Jun-29-2020 13:27:41 (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
Jun-29-2020 13:27:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 71	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jun-29-2020 13:27:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Jun-29-2020 13:27:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 80	Initial Entry
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Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Collection Date:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jun/29/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jun-29-2020 13:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Category CLINICA for Lab T L CHEMI est: STRY Subcatego BLOOD ry for La CHEMIS b Test: TRY	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Lab Sub- Panel Collected: YES	
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3.a Lab Panel:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: BLOOD CHEMISTRY	Initial Entry

3.a Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

3.b

Date	Location	User	Value	Reason
Jun-29-2020 13:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Category fo HEMAT r Lab Test: OLOGY Subcategor DIFFER y for Lab T ENTIA est: L Lab Sub-Pa YES nel Collecte d:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

3.b Lab Panel:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEMATOLOGY	Initial Entry

3.b Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: DIFFERENTIAL	Initial Entry

3.b Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jun-29-2020 13:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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: 10071050

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
Jun-29-2020 13:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-29-2020 13:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-29-2020 14:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-29-2020 13:26:57	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V3_WEEK1_POSTVAX1_S**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:** 10071050**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.
Jun-29-2020 13:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Jun/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-29-2020 14:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBT2 : P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-29-2020 14:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBT2P	Initial Entry

5.b

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-29-2020 14:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBT2 : R	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jun-29-2020 14:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBT2R	Initial Entry

5.c

Date	Location	User	Value	Reason
Jun-29-2020 14:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBT2 : S	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sample ID

Date	Location	User	Value	Reason
Jun-29-2020 14:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBT2S	Initial Entry

5.d

Date	Location	User	Value	Reason
Jun-29-2020 14:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBT2 : T	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jun-29-2020 14:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBT2T	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-29-2020 14:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBT2 : V	Initial Entry
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5.e Sample ID

Date	Location	User	Value	Reason
Jun-29-2020 14:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBT2V	Initial Entry

5.f

Date	Location	User	Value	Reason
Jun-29-2020 14:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY2F : B	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.f Sample ID

Date	Location	User	Value	Reason
Jun-29-2020 14:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY2FB	Initial Entry

5.g

Date	Location	User	Value	Reason
Jun-29-2020 14:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY2F : C	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jun-29-2020 14:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY2FC	Initial Entry

5.h

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-29-2020 14:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY2F : D	Initial Entry
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5.h Sample ID

Date	Location	User	Value	Reason
Jun-29-2020 14:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY2FD	Initial Entry

5.i

Date	Location	User	Value	Reason
Jun-29-2020 14:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY2F : F	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.i Sample ID

Date	Location	User	Value	Reason
Jun-29-2020 14:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY2FF	Initial Entry

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071050

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
Jul-13-2020 14:21:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/13/2020	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V4_WEEK3_VAX2_S**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071050**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom:: F E V E R Were fever or sys N temic symptoms O present on the las t day the Subject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom:: FA TI G U E Were fever or sys N temic symptoms O present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Symptom:

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

			Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	
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2.c Symptom:

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47	ACV0PFEINFP6000	Laura Pace	Data Entry: Symptom:: C	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V4_WEEK3_VAX2_S**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071050**Subject Initials:** ---**Generated By:** pfe.lpace**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-05:00) Eastern Time (US & Canada)		(pfe.lpace)	HI L LS N O	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.d Symptom:

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom:: VO MI TI NG Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

2.f

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<p>Data Entry:</p> <p>Symptom:: DI AR RH EA</p> <p>Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:</p>	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

2.f Symptom:

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom:: NEW OR W ORSE NED MUSC LE PA IN	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

			Were fever or NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? :	
--	--	--	---	--

2.g Symptom:

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

<p>Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Laura Pace (pfe.lpace)</p>	<p>Data Entry: Symptom:: NEW OR W ORSE NED J OINT PAIN Were fever or NO systemic sym ptoms presen t on the last d ay the Subjec t Diary was c ompleted?:</p>	<p>Initial Entry</p>
--	------------------------	---------------------------------------	--	----------------------

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

2.h Symptom:

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: RIGHT	Initial Entry
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5.a

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Injection Site Reaction: REDNESS Were injection site reactions present on the last day of the Subject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: REDNESS	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Injection Site Reaction: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Injection Site Reaction:: PAIN AT I NJE CTIO N SI TE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

			Were injection NO site reactions present on the last day the Subject Diary was completed?:	
--	--	--	--	--

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-13-2020 14:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Exam Date:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Not Applicable Result: Not Applicable	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

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Subject Initials: ---

Generated By: pfe.levisse

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

2.a Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: Not Applicable Result: Not Applicable	Initial Entry

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Visit: V4_WEEK3_VAX2_S

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

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2.b Body System Examined:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

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2.c Body System Examined:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

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2.d Body System Examined:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

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2.e Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

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2.f Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

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Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.i

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

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Header Text: c4591001

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Date	Location	User	Value	Reason
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2.i Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Result:	Initial Entry

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2.j Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.k

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined : Result:	Initial Entry

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Visit: V4_WEEK3_VAX2_S

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Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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2.m Body System Examined:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.n

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined Not Applicable : Result: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Not Applicable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:54

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: VITAL SIGNS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/13/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-13-2020 14:25:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier: 1 Temperature: 36.9 Temperature Unit: Temperature Location: ORAL CAVITY Systolic: 119 Diastolic: 77 BP Position: SITTING : G Pulse: 75	Initial Entry

2.a Record Identifier:

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jul-13-2020 14:25:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 36.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:42 (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
Jul-13-2020 14:25:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

& Canada)

2.a Systolic:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 119	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 77	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:54

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: VITAL SIGNS - 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

Jul-13-2020 14:25:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 75	Initial Entry
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Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/13/2020	Initial Entry

4. Laboratory Name and Address (Derived)

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jul-13-2020 14:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jul-13-2020 14:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIVE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 19-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Not Done ::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Choriogonadotropin B eta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEGATIVE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10071050

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
Jul-13-2020 14:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-13-2020 14:22:21 (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
Jul-13-2020 17:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-13-2020 14:22:21	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V4_WEEK3_VAX2_S**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:** 10071050**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.
Jul-13-2020 14:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Jul/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-13-2020 17:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBTD : 8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-13-2020 17:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBTD8	Initial Entry

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:05

Site No: 1007

Subject No: 10071050

Generated By: pfe.levissc

Form: MICROBIOLOGY SPECIMEN - 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
Jul-13-2020 14:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

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
Jul-13-2020 14:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/13/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jul-13-2020 14:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SWABBED MATERIA L	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jul-13-2020 14:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL CAVITY	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-13-2020 14:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RES P SYNDROME CORO NAVIRUS 2	Initial Entry
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5. Device Type:

Date	Location	User	Value	Reason
Jul-13-2020 14:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jul-13-2020 14:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CEPHEID XPERT XP RESS SARS-COV-2 T EST	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jul-13-2020 14:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEGATIVE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)				
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Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: CENTRAL LAB SAMPLE COLLECTION -
eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Collection Date:

Date	Location	User	Value	Reason
Jul-13-2020 14:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/13/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jul-13-2020 14:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jul-13-2020 14:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Category CLINICA for Lab T L CHEMI est: STRY Subcatego BLOOD ry for La CHEMIS b Test: TRY	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Lab Sub- Panel Collected: YES	
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3.a Lab Panel:

Date	Location	User	Value	Reason
Jul-13-2020 14:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-13-2020 14:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: BLOOD CHEMISTRY	Initial Entry

3.a Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jul-13-2020 14:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

3.b

Date	Location	User	Value	Reason
Jul-13-2020 14:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Category fo HEMAT r Lab Test: OLOGY Subcategor DIFFER y for Lab T ENTIA est: L Lab Sub-Pa YES nel Collecte d:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

3.b Lab Panel:

Date	Location	User	Value	Reason
Jul-13-2020 14:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEMATOLOGY	Initial Entry

3.b Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-13-2020 14:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: DIFFERENTIAL	Initial Entry

3.b Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jul-13-2020 14:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071050

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
Jul-13-2020 14:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-13-2020 14:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-13-2020 18:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-13-2020 14:22:06	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V4_WEEK3_VAX2_S**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:** 10071050**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.
Jul-13-2020 14:22:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Jul/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-13-2020 18:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBTF : G	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-13-2020 18:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBTFG	Initial Entry

5.b

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jul-13-2020 18:00:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBTF : H	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-13-2020 18:00:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBTFH	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-13-2020 18:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBTF : J	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sample ID

Date	Location	User	Value	Reason
Jul-13-2020 18:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBTFJ	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-13-2020 18:01:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBTF : K	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jul-13-2020 18:01:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBTFK	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-13-2020 18:01:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNBTF : L	Initial Entry
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5.e Sample ID

Date	Location	User	Value	Reason
Jul-13-2020 18:01:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNBTFL	Initial Entry

5.f

Date	Location	User	Value	Reason
Jul-13-2020 18:01:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY2P : G	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.f Sample ID

Date	Location	User	Value	Reason
Jul-13-2020 18:01:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY2PG	Initial Entry

5.g

Date	Location	User	Value	Reason
Jul-13-2020 18:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY2P : H	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jul-13-2020 18:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY2PH	Initial Entry

5.h

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-13-2020 18:01:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY2P : J	Initial Entry
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5.h Sample ID

Date	Location	User	Value	Reason
Jul-13-2020 18:01:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY2PJ	Initial Entry

5.i

Date	Location	User	Value	Reason
Jul-13-2020 18:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY2P : K	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.i Sample ID

Date	Location	User	Value	Reason
Jul-13-2020 18:01:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY2PK	Initial Entry

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071050

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
Jul-13-2020 15:40:26 (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
Jul-13-2020 15:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jul-13-2020 15:40:26 (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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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-13-2020 15:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/13/2020 15:08	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jul-13-2020 15:40:26 (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
Jul-13-2020 15:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jul-13-2020 15:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

8. Actual Dose:

Date	Location	User	Value	Reason
Jul-13-2020 15:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 0.5	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jul-13-2020 15:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: mL	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jul-13-2020 15:40:26 (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
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071050

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

Jul-13-2020 15:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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: 10071050

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
Jul-17-2020 12:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	V Swetha (pfe.swethv01)	Query 1: Closed	Response satisfies query
Jul-17-2020 11:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	confirmed date is correct; Sponsor correspondence uploaded for guidance of out of window Visit 5 scheduled for 16JUL2020; subject was not available for visit
Jul-17-2020 10:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pankaj Bhoir (pfe.bhoirp02)	Query 1: Opened	PDQ: Date of visit at this visit is out of window (-3 days) from Date of visit (13/Jul/2020) at V4WK3VX2 visit. Please reconcile and

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

				update accordingly, else confirm date is correct as is.
Jul-16-2020 14:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/16/2020	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Exam Date:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/16/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: GENERAL APPEARANCE Result: NOT DONE	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: GENERAL APPEARANCE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.a Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System SKIN Examined: Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SKIN	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System HEAD Examined: Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.c Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEAD	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System EYES Examined: Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EYES	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: EARS Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EARS	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System NOSE Examined: Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOSE	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System THRO Examined: AT Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: THROAT	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System HEAR Examined: T Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEART	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.i

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: LUNG S Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.i Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: LUNGS	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System ABDO Examined: MEN Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.j Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ABDOMEN	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.k

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body Syst MUSCUL em Exami OSKELE ned: TAL Result: NOT DO NE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.k Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: MUSCULOSKELETA L	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examine d: EXTREMITIES Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EXTREMITIES	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System NEURO m Examine LOGIC d: AL Result: NOT DO NE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.m Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEUROLOGICAL	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.n

Date	Location	User	Value	Reason
Aug-06-2020 08:22:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Bod LYMPH NODE y S S yste m E xa min ed:	Changed Information

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			<p>Res ABNORMAL ult: <i>If abnormal findings, specify: (If clinically significant, record on the Medical History or Adverse Event CRF as appropriate).</i></p> <p>has 1x2 cm non-tender, mobile node in right axillae</p> <p>Are there clinically significant findings?</p> <p>YES</p>	
<p>Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Laura Pace (pfe.lpace)</p>	<p>Data Entry: Bod LYMPH NODE y S S yste m E xa min ed:</p>	<p>Initial Entry</p>

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			<p>Res ABNORMAL ult: <i>If abnormal findings, specify: (If clinically significant, record on the Medical History or Adverse Event CRF as appropriate).</i></p> <p>has 1x2 cm non-tender, mobile node in right axillae</p> <p>Are there clinically significant findings?</p> <p>NO</p>	
--	--	--	---	--

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: LYMPH NODES	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Aug-06-2020 09:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Closed	Response satisfies query
Aug-06-2020 08:22:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-06-2020 08:22:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ABNORMAL <i>If abnormal findings, specify: (If clinically significant, record on the Medical History or Adverse Event CRF as app</i>	Changed Information

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			<p>ropriate).</p> <p>has 1x2 cm non-tender, mobile node in right axillae</p> <p>Are there clinically significant findings?</p> <p>YES</p>	
<p>Jul-30-2020 04:09:07 (UTC-05:00) Eastern Time (US & Canada)</p>	ACV0PFEINFP6000	<p>Ahmed Hassan (pfe.hassaa38)</p>	<p>Query 1: Reissued :Opened</p>	<p>Please can you confirm if PI has received MM input? If so, please update as appropriate. Thanks</p>
<p>Jul-23-2020 10:59:39 (UTC-05:00) Eastern Time (US & Canada)</p>	ACV0PFEINFP6000	<p>Susan Parker (pfe.sparker)</p>	<p>Query 1: Answered</p>	<p>Acknowledged. Query will remain open until resolution.</p>
<p>Jul-23-2020 06:04:40 (UTC-05:00) Eastern Time (US & Canada)</p>	ACV0PFEINFP6000	<p>Ahmed Hassan (pfe.hassaa38)</p>	<p>Query 1: Reissued :Opened</p>	<p>Sure - please leave the query as open until resolution. Thank you</p>

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-22-2020 16:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Susan Parker (pfe.sparker)	Query 1: Answered	PI has requested Medical Monitor input. Thank you.
Jul-21-2020 11:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Reissued :Opened	It is correct that the abnormal result is listed in the AE log as we now have oversight it is related to study IP. However, as a result, this needs to be expressed as a clinically significant finding as per 8.8.4 (eCRF) Please update as appropriate.

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

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2.n Result:

Date	Location	User	Value	Reason
Jul-20-2020 14:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Susan Parker (pfe.sparker)	Query 1: Answered	The finding was determined not to be clinically significant. Please advise how to otherwise capture this finding if the AE is removed. Thank you.
Jul-20-2020 06:49:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Reissued :Opened	As per section 8.8.4 of eCRF completion requirements, if an abnormal result is clinically significant, it should be listed in the AE log. If the result is not, please remove from the AE log. Please review

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

				and update as appropriate.
Jul-17-2020 15:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	per PI:The adenopathy is not clinically significant. She has no pain with it & there is no alteration in function of the arm. But it is there & she noticed & brought to my attention. So, to me, that is an adverse event that is not clinically significant.
Jul-17-2020 06:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Opened	Are there clinically significant findings listed as 'No', however, this event is listed as an AE. Please can you review and update as appropriate

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

<p>Jul-16-2020 14:29:00 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Laura Pace (pfe.lpace)</p>	<p>Data Entry: ABNORMAL <i>If abnormal findings, specify: (If clinically significant, record on the Medical History or Adverse Event CRF as appropriate).</i></p> <p>has 1x2 cm non-tender, mobile node in right axillae</p> <p>Are there clinically significant findings?</p> <p>NO</p>	<p>Initial Entry</p>
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 06-Jul-2020 21:54

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: VITAL SIGNS - 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
Jul-16-2020 14:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/16/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-16-2020 14:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier:: 1 Temperature: 36.9 Temperature Unit: Temperature Location: ORAL CAVITY Systolic:: 124 Diastolic:: 81 BP Position: SITTING : G Pulse:: 70	Initial Entry

2.a Record Identifier:

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jul-16-2020 14:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jul-16-2020 14:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 36.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jul-16-2020 14:27:07 (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
Jul-16-2020 14:27:07 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

& Canada)

2.a Systolic:

Date	Location	User	Value	Reason
Jul-16-2020 14:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 124	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jul-16-2020 14:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 81	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jul-16-2020 14:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Jul-16-2020 14:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 70	Initial Entry
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Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Collection Date:

Date	Location	User	Value	Reason
Jul-16-2020 14:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/16/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jul-16-2020 14:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jul-16-2020 14:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Category CLINICA for Lab T L CHEMI est: STRY Subcatego BLOOD ry for La CHEMIS b Test: TRY	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

			Lab Sub- Panel Collected: YES	
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3.a Lab Panel:

Date	Location	User	Value	Reason
Jul-16-2020 14:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-16-2020 14:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: BLOOD CHEMISTRY	Initial Entry

3.a Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jul-16-2020 14:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

3.b

Date	Location	User	Value	Reason
Jul-16-2020 14:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Category fo HEMAT r Lab Test: OLOGY Subcategor DIFFER y for Lab T ENTIA est: L Lab Sub-Pa YES nel Collecte d:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: CENTRAL LAB SAMPLE COLLECTION -
eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

3.b Lab Panel:

Date	Location	User	Value	Reason
Jul-16-2020 14:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEMATOLOGY	Initial Entry

3.b Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-16-2020 14:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: DIFFERENTIAL	Initial Entry

3.b Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jul-16-2020 14:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071050

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
Jul-16-2020 14:22:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-16-2020 14:22:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-16-2020 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-16-2020 14:22:25	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V5_WEEK1_POSTVAX2_S**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:** 10071050**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.
Jul-16-2020 14:22:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: YES Date of Collection: Jul/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-16-2020 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BP74P : H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-16-2020 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BP74PH	Initial Entry

5.b

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jul-16-2020 14:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID: BP74PJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-16-2020 14:22:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BP74PJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-16-2020 14:22:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BP74P : K	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sample ID

Date	Location	User	Value	Reason
Jul-16-2020 14:22:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BP74PK	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-16-2020 14:22:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID: BP74PL	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jul-16-2020 14:22:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BP74PL	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-16-2020 14:22:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BP74P : M	Initial Entry
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5.e Sample ID

Date	Location	User	Value	Reason
Jul-16-2020 14:22:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BP74PM	Initial Entry

5.f

Date	Location	User	Value	Reason
Jul-16-2020 14:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY2V : L	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.f Sample ID

Date	Location	User	Value	Reason
Jul-16-2020 14:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY2VL	Initial Entry

5.g

Date	Location	User	Value	Reason
Jul-16-2020 14:23:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BNY2V D: M	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jul-16-2020 14:23:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY2VM	Initial Entry

5.h

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-16-2020 14:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BNY2V D: N	Initial Entry
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5.h Sample ID

Date	Location	User	Value	Reason
Jul-16-2020 14:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY2VN	Initial Entry

5.i

Date	Location	User	Value	Reason
Jul-16-2020 14:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY2V : P	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.i Sample ID

Date	Location	User	Value	Reason
Jul-16-2020 14:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY2VP	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jul-27-2020 13:49:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/27/2020	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V6_WEEK2_POSTVAX2_S**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:54**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071050**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom:: F E V E R Were fever or sys N temic symptoms O present on the las t day the Subject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: FEVER	Initial Entry
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom:: FA TI G U E Were fever or sys N temic symptoms O present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

2.b Symptom:

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

			Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	
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2.c Symptom:

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27	ACV0PFEINFP6000	Laura Pace	Data Entry: Symptom:: C	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lpace

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.lpace)	HI L LS N O	Were fever or systemic symptoms present on the last day the Subject Diary was completed?:
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2.d Symptom:

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom:: VO MI TI NG Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

2.f

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom:: DI AR RH EA Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

2.f Symptom:

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Symptom:: NEW OR W ORSE NED MUSC LE PA IN	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

			Were fever or NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? :	
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2.g Symptom:

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

<p>Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Laura Pace (pfe.lpace)</p>	<p>Data Entry: Symptom:: NEW OR W ORSE NED J OINT PAIN Were fever or NO systemic sym ptoms presen t on the last d ay the Subjec t Diary was c ompleted?:</p>	<p>Initial Entry</p>
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Symptom:

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: RIGHT	Initial Entry
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5.a

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Injection Site Reaction: RE D NE SS Were injection site reactions present on the last day the Subject Diary was completed?: N O	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: REDNESS	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Injection Site Reaction: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Injection Site Reaction:: PAIN AT I NJE CTIO N SI TE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

			Were injection NO site reactions present on the last day the Subject Diary was completed?:	
--	--	--	--	--

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jul-27-2020 13:52:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Exam Date:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: GENERAL APPEARANCE Result: NOT DONE	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: GENERAL APPEARANCE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.a Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System SKIN Examined: Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SKIN	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System HEAD Examined: Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.c Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEAD	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: EYES Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EYES	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: EARS Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EARS	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: NOSE Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOSE	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: THRO AT Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: THROAT	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: HEAR T Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: HEART	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.i

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: LUNG S Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.i Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: LUNGS	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-27-2020 13:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: ABDO MEN Result: NOT DONE	Initial Entry
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examined: ABDO MEN Result:	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)

2.j Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ABDOMEN	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.k

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body Syst MUSCUL em Exami OSKELE ned: TAL Result: NOT DO NE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.k Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: MUSCULOSKELETA L	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examine d: EXTREMITIES Result: NOT DONE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: EXTREMITIES	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System NEURO m Examine LOGIC d: AL Result: NOT DO NE	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.m Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NEUROLOGICAL	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NOT DONE	Initial Entry

2.n

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Body System Examine d: LYMPH NODES Result: NORMAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: LYMPH NODES	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jul-27-2020 13:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NORMAL	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form Version: 17-Jul-2020 21:54

Site No: 1007

Subject No: 10071050

Generated By: pfe.lewissc

Form: VITAL SIGNS - 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
Jul-27-2020 13:50:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-27-2020 13:50:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Record Identifier:: 1 Temperature: 36.5 Temperature Unit: Temperature Location: ORAL CAVITY Systolic:: 137 Diastolic:: 83 BP Position: SITTING G Pulse:: 78	Initial Entry

2.a Record Identifier:

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jul-27-2020 13:50:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jul-27-2020 13:50:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 36.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jul-27-2020 13:50:14 (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
Jul-27-2020 13:50:14 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

& Canada)

2.a Systolic:

Date	Location	User	Value	Reason
Jul-27-2020 13:50:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 137	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jul-27-2020 13:50:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 83	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jul-27-2020 13:50:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Jul-27-2020 13:50:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 78	Initial Entry
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Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071050

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
Jul-27-2020 13:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-27-2020 13:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-27-2020 14:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-27-2020 13:50:45	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V6_WEEK2_POSTVAX2_S**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:** 10071050**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.
Jul-27-2020 13:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Jul/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-27-2020 14:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BP74Y : L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-27-2020 14:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BP74YL	Initial Entry

5.b

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jul-27-2020 14:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BP74Y : M	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-27-2020 14:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BP74YM	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-27-2020 14:11:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BP74Y : N	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sample ID

Date	Location	User	Value	Reason
Jul-27-2020 14:11:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BP74YN	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-27-2020 14:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BP74Y : P	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jul-27-2020 14:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BP74YP	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-27-2020 14:11:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BP74Y : R	Initial Entry
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5.e Sample ID

Date	Location	User	Value	Reason
Jul-27-2020 14:11:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BP74YR	Initial Entry

5.f

Date	Location	User	Value	Reason
Jul-27-2020 14:12:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY31 : Y	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.f Sample ID

Date	Location	User	Value	Reason
Jul-27-2020 14:12:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY31Y	Initial Entry

5.g

Date	Location	User	Value	Reason
Jul-27-2020 14:12:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY31 : Z	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jul-27-2020 14:12:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY31Z	Initial Entry

5.h

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-27-2020 14:12:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY32 : 0	Initial Entry
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5.h Sample ID

Date	Location	User	Value	Reason
Jul-27-2020 14:12:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY320	Initial Entry

5.i

Date	Location	User	Value	Reason
Jul-27-2020 14:12:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY32 : 1	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

5.i Sample ID

Date	Location	User	Value	Reason
Jul-27-2020 14:12:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY321	Initial Entry

5.j

Date	Location	User	Value	Reason
Jul-27-2020 14:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY32 : 2	Initial Entry

5.j Sample ID

Date	Location	User	Value	Reason
Jul-27-2020 14:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY322	Initial Entry

5.k

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-27-2020 14:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BNY32 : 3	Initial Entry
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5.k Sample ID

Date	Location	User	Value	Reason
Jul-27-2020 14:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BNY323	Initial Entry

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Header Text: c4591001

Visit: V7_MONTH1_S

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071050

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-10-2020 13:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Aug/10/2020	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V7_MONTH1_S

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071050

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
Aug-10-2020 13:26:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-10-2020 13:26:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-10-2020 17:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-10-2020 13:26:02	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V7_MONTH1_S**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:** 10071050**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.
Aug-10-2020 13:26:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Aug/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-10-2020 17:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BM811 : Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 17:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BM811Z	Initial Entry

5.b

Header Text: c4591001

Visit: V7_MONTH1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-10-2020 17:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BM812 : 0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 17:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BM8120	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-10-2020 17:31:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BM812 : 1	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V7_MONTH1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 17:31:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BM8121	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-10-2020 17:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BM812 : 2	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 17:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BM8122	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V7_MONTH1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

Aug-10-2020 17:31:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BM812 : 3	Initial Entry
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 17:31:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BM8123	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-10-2020 17:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BPG03 : B	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V7_MONTH1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.f Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 17:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BPG03B	Initial Entry

5.g

Date	Location	User	Value	Reason
Aug-10-2020 17:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BPG03 : C	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 17:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BPG03C	Initial Entry

5.h

Date	Location	User	Value	Reason
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090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V7_MONTH1_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-10-2020 17:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BPG03 : D	Initial Entry
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5.h Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 17:32:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BPG03D	Initial Entry

5.i

Date	Location	User	Value	Reason
Aug-10-2020 17:32:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BPG03 : F	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V7_MONTH1_S

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071050

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

5.i Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 17:32:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BPG03F	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V8_MONTH6_S

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071050

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-04-2021 10:20:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/4/2021	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V8_MONTH6_S

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071050

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
Jan-04-2021 10:20:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-04-2021 10:20:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-04-2021 12:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-04-2021 10:20:53	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001**Visit:** V8_MONTH6_S**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:** 10071050**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.
Jan-04-2021 10:20:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: YES Date of Collection: Jan/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-04-2021 12:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BR3YD : D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 12:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BR3YDD	Initial Entry

5.b

Header Text: c4591001

Visit: V8_MONTH6_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jan-04-2021 12:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample I BMNR6 D: L	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 12:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BMNR6L	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-04-2021 12:44:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: Sample ID BMNR6 : S	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

Header Text: c4591001

Visit: V8_MONTH6_S

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: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 12:44:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	Data Entry: BMNR6S	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:05 **Form Status:** Data Complete, Locked, Frozen, Verified

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

Subject No: 10071050 **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
Aug-10-2020 13:26:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Aug/10/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-10-2020 13:26:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-10-2020 13:26:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: COMPLETED	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)

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: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

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Date	Location	User	Value	Reason
Jul-16-2020 14:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

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, Locked, Frozen

Site No: 1007

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

Subject No: 10071050

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
Jul-16-2020 14:34:54 (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
Jul-16-2020 14:34:54 (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
Jul-22-2020 12:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 2: Closed	Response satisfies query
Jul-22-2020 09:48:58	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

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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, Locked, Frozen

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)				
Jul-22-2020 09:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Susan Parker (pfe.sparker)	Data Entry: Right axillary lymph node enlargement	Changed Information
Jul-21-2020 11:40:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 2: Opened	Please consider updating the event term "Right axilla lump" to a more specific term as "Right axillary lymph node enlargement"
Jul-20-2020 06:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Closed	Response satisfies query
Jul-17-2020 15:16:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	This is a mild, benign adenopathy in the right axillae.
Jul-17-2020 06:30:38	ACV0PFEINFP6000	Ahmed Hassan	Query 1: Opened	Please can you provide a

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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, Locked, Frozen

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.hassaa38)		diagnosis, if available, for this AE? If not, please can you confirm if the mass is benign or malignant, if known.
Jul-16-2020 14:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Right axilla lump	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jul-16-2020 14:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jul/15/2020 UNK:UN K	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jul-27-2020 13:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO End Date Time: Jul/27/2020 UNK:	New Information

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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, Locked, Frozen

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

			UNK	
Jul-16-2020 14:34:54 (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
Jul-16-2020 14:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jul-16-2020 14:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

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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, Locked, Frozen

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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

**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
Jul-16-2020 14:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jul-20-2020 06:49:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Closed	Response satisfies query
Jul-17-2020 15:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	per PI:I called related because it is in the same arm as the vaccine and the area where the shot was given has lymph node drainage into the axillae.

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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, Locked, Frozen

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.levisse

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Jul-17-2020 06:32:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Opened	Please can you confirm in the PI's judgment why this AE is felt to be related to IP?
Jul-16-2020 14:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jul-16-2020 14:34:54 (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
Jul-16-2020 14:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae402a\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, Locked, Frozen

Site No: 1007

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

Subject No: 10071050

Subject Initials: ---

Generated By: pfe.lewissc

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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jul-16-2020 14:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-27-2020 13:53:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jul-16-2020 14:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: NO	Initial Entry

090177e196ae402a\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: 10071050 **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
Feb-22-2021 20:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Dec/28/2020	Changed Information
Feb-16-2021 16:06:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/5/2021	Initial Entry

090177e196ae402a\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: 10071050 **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-16-2021 19:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-16-2021 16:06:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-16-2021 16:06:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Participant is willing to return for Vaccina tion 3 Participant is: eligible and NOT confirmed to hav e received only pl	Initial Entry

090177e196ae402a\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: 10071050 **Subject Initials:** ---

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

			acebo at Vaccinat ion 1/2	
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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: 10071050

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-16-2021 19:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Jan/4/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-16-2021 19:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

090177e196ae402a\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:** 10071050**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Aug-10-2020 13:26:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jun-22-2020 11:53:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jun-22-2020 11:37:40 (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
Aug-10-2020 13:26:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/10/2020	Initial Entry
Jun-22-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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: 10071050

Subject Initials: ---

Generated By: pfe.levissc

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

11:53:05 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Jun/22/2020	
Jun-22-2020 11:37:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jun/22/2020	Initial Entry

090177e196ae402a\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: 10071050

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Aug-12-2020 14:23:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae402a\Final\Final On: 01-Apr-2021 05:31 (GMT)