

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** COHORT\_SELECTION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[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	06 OCT 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

<b>Header Text:</b> c4591001	<b>Form:</b> MAIN INFORMED CONSENT
<b>Visit:</b> COHORT_SELECTION	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1007) Cincinnati Children's Hospital Medical Center
<b>Site No:</b> 1007	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10071443	<b>Generated Time (GMT):</b> 19-Apr-2021 21:04
<b>Generated By:</b> pfe.levisse	

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Nov/4/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10071443]
2.	Birth Date:	(b) (6)/2003
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/4/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

<b>Header Text:</b> c4591001	<b>Form:</b> DISPOSITION - SCREENING
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 15-Sep-2020 21:52	<b>Site Name:</b> (1007) Cincinnati Children's Hospital Medical Center
<b>Site No:</b> 1007	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10071443	<b>Generated Time (GMT):</b> 19-Apr-2021 21:04
<b>Generated By:</b> pfe.levisse	

[eCRF Audit Trail History](#)

**Disposition - Screening**

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

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Acne]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> HIV STATUS
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 15-Sep-2020 21:57	<b>Site Name:</b> (1007) Cincinnati Children's Hospital Medical Center
<b>Site No:</b> 1007	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10071443	<b>Generated Time (GMT):</b> 19-Apr-2021 21:04
<b>Generated By:</b> pfe.levisse	

[eCRF Audit Trail History](#)

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



**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - BASELINE

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/4/2020
2.	Weight:	[53.2]
3.	Unit:	kg
4.	Height:	[161.0]
5.	Unit:	cm
6.	Body Mass Index:	[20.5]

**Vital Signs Details**

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

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 10-Oct-2020 15:58  
**Site No:** 1007  
**Subject No:** 10071443  
**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1007) Cincinnati Children's Hospital Medical Center  
**Subject Initials:** ---  
**Generated Time (GMT):** 19-Apr-2021 21:04

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS	<a href="#">Comments</a>
2.	Lab Sub-Panel:	PREGNANCY	<a href="#">Comments</a>
3.	Collection Date:	Nov/4/2020	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	[STUDY SITE]	<a href="#">Comments</a>
5.	Specimen Type:	URINE	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	[113]	<a href="#">Comments</a>
	Test:	Choriogonadotropin Beta_PX113	
	Result:	NEGATIVE	<a href="#">Comments</a>
	Not Done:		<a href="#">Comments</a>

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** RANDOMIZATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Nov/4/2020
2.	Randomization Number:	[115649]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/4/2020
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	[BPYVBB]
5.b	Sample ID	[BMRW56]
5.c	Sample ID	[BMRW57]

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**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/4/2020
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	[BPYVB9]
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**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L **Form:** VACCINATION  
**Form Version:** 22-Apr-2020 21:04 **Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center  
**Subject No:** 10071443 **Subject Initials:** ---  
**Generated By:** pfe.levisse **Generated Time (GMT):** 19-Apr-2021 21:04

**eCRF Audit Trail History**

**Vaccination**

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

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> REACTOGENICITY DIARY
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 06-Jul-2020 21:53	<b>Site Name:</b> (1007) Cincinnati Children's Hospital Medical Center
<b>Site No:</b> 1007	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10071443	<b>Generated Time (GMT):</b> 19-Apr-2021 21:04
<b>Generated By:</b> pfe.levisse	

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/25/2020
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - TEMP

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/25/2020
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**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Nov/25/2020
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:	

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/25/2020
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	[BP90D7]
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**Header Text:** c4591001  
**Visit:** V2\_VAX2\_L  
**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1007  
**Subject No:** 10071443  
**Generated By:** pfe.levisse

**Form:** VACCINATION  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1007) Cincinnati Children's Hospital Medical Center  
**Subject Initials:** ---  
**Generated Time (GMT):** 19-Apr-2021 21:04

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/25/2020 09:11
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/21/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP90ZN]
5.b	Sample ID	[BMNR2V]
5.c	Sample ID	[BMNR2W]

**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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	
<b>COVID-19 Illness Visit</b>		
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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:	[ ]
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**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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** 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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** 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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**Health Care Utilization**

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

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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**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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

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

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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**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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Grand Mal Seizure	Nov/29/2020 UNK:UNK	NO End Date Time:  Nov/29/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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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)	[Grand Mal Seizure]
4.	Start Date Time:	Nov/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/29/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Not related as have additional data now showing relatedness to other cause]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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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	[ ]

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**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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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**Concomitant Medications**

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

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**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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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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?	

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**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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**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?	

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<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME - MONTH 1
<b>Visit:</b> Unplanned Vaccination - Unscheduled	<b>Form Status:</b> Not Started
<b>Form Version:</b> 10-Oct-2020 15:57	<b>Site Name:</b> (1007) Cincinnati Children's Hospital Medical Center
<b>Site No:</b> 1007	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10071443	<b>Generated Time (GMT):</b> 19-Apr-2021 21:04
<b>Generated By:</b> pfe.levisse	

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 10-Dec-2020 02:29

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

**Header Text:** c4591001

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

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/25/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
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**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Feb/10/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
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**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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**Death Details**

1.	Date of Collection / Notification of Death:	//
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**Cause of Death**

2.	Cause of Death Status:	
	Cause of Death:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/24/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/24/2021
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**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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**Exclusion Criteria Met**

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

**Visit:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Feb/24/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/24/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/24/2021
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	[BR100L]
5.b	Sample ID	[BSB79L]
5.c	Sample ID	[BSB79M]

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/24/2021
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	[BR100K]
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090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** VACCINATION

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/24/2021 11:07
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Lab Urinalysis**

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

**Lab Result**

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

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:** V102\_VAX4

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** VACCINATION

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**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?	

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Not Started

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/21/2020



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisc

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.leviscc

**Generated Time (GMT):** 19-Apr-2021 21:04

[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-10-2021 14:45:57 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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Item	Date	User	Comment
Form	Nov-04-2020 14:04:37 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
Form	Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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Item	Date	User	Comment
1	Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
1	Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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Item	Date	User	Comment
2	Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
2	Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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Item	Date	User	Comment
3	Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
3	Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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Item	Date	User	Comment
4	Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
4	Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable



**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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Item	Date	User	Comment
5	Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
5	Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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Item	Date	User	Comment
6.a	Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
6.a	Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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Item	Date	User	Comment
6.a	Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
6.a	Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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Item	Date	User	Comment
6.a	Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	
6.a	Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	Laura Pace (pfe.lpace)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

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Item	Date	User	Comment
Form	Feb-24-2021 10:55:02 (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:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Robert Frenck	Approved	Mar-10-2021 14:45:57 (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-24-2021 10:53:44 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
------------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Robert Frenck	Approved	Jan-23-2021 20:18:36 (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.

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Nov-04-2020 13:49:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 13:49:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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*I. Consent Was:*

Date	Location	User	Value	Reason
Nov-04-2020 13:49:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Nov/4/2020	Initial Entry



Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071443

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Subject ID**

Date	Location	User	Value	Reason
Nov-04-2020 13:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 10071443	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Nov-04-2020 13:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6) /2003	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Nov-04-2020 13:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Nov-04-2020 13:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 13:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-04-2020 14:04:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-04-2020 14:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-04-2020 14:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-04-2020 14:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071443

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 19-Apr-2021 21:04

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*I.a*

Date	Location	User	Value	Reason
Nov-04-2020 14:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 1 Medical History Term: Depression Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Nov-04-2020 14:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 14:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Depression	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Nov-04-2020 14:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Nov-04-2020 14:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Nov-04-2020 14:29:43	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071443

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	<b>Line/MH Number:</b> 2 <b>Medical History Term:</b> Anxiety <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> YES	
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**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Nov-04-2020 14:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 14:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Anxiety	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Nov-04-2020 14:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Nov-04-2020 14:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Nov-04-2020 14:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Insomnia <b>Start Date:</b> UNK/UNK/2016 <b>Ongoing:</b> YES	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071443

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Nov-04-2020 14:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 14:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Insomnia	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Nov-04-2020 14:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Nov-04-2020 14:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Nov-04-2020 14:30:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> Acne <b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> YES	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071443

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Nov-04-2020 14:30:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Nov-07-2020 19:20:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Closed	Response satisfies query
Nov-06-2020 10:59:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	updated
Nov-05-2020 20:03:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Opened	ClinQuery: v1: Please can you update the medhx log to indicate why a pregnancy test was not done for this subject? There is nothing to currently indicate she is not a WOBCP. Thanks
Nov-04-2020 14:30:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Acne	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Nov-04-2020 14:30:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Nov-04-2020 14:30:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

**Form:** HIV STATUS - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Nov-04-2020 14:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> The subject is NOT known to be HIV P OSITIVE	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1007

Subject No: 10071443

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Date:**

Date	Location	User	Value	Reason
Nov-04-2020 14:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Nov-04-2020 14:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 53.2	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Nov-04-2020 14:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Nov-04-2020 14:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-04-2020 14:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 161.0	Changed Information
Nov-04-2020 14:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Height 61 is outside of Normal Range 140 - 198 for cm or 55 - 80 for in.
Nov-04-2020 14:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 61.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Nov-04-2020 14:31:09 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> cm	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071443

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 19-Apr-2021 21:04

(US & Canada)

6. Body Mass Index:

Date	Location	User	Value	Reason
Nov-04-2020 14:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 20.5	Changed Information
Nov-04-2020 14:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 143.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Nov-04-2020 14:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.6 <b>Temperature Unit:</b> C <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Nov-04-2020 14:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Nov-04-2020 14:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Nov-04-2020 14:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

Nov-04-2020 14:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071443

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-06-2020 10:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry
Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b>	Initial Entry
Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Nov-06-2020 10:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry
Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b>	Initial Entry
Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-06-2020 10:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Nov/4/2020	Initial Entry
Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b>	Initial Entry
Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071443

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Nov-06-2020 10:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry
Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b>	Initial Entry
Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Nov-06-2020 10:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry
Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b>	Initial Entry
Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Nov-06-2020 10:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Not Applicable <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry
Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Not Applicable <b>Result::</b> <b>Not Done::</b>	Initial Entry
Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> <b>Result::</b> <b>Not Done::</b>	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071443

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

			Test::	Not Applicable
			Result::	Not Applicable
			Not Done::	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-06-2020 10:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 113	Initial Entry
Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u>	Initial Entry
Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Nov-06-2020 10:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> NEGATIVE	Initial Entry
Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u>	Initial Entry
Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Nov-06-2020 10:59:01 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u>	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

(US & Canada)				
Nov-04-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Nov-04-2020 14:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Nov-04-2020 14:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 115649	Initial Entry



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071443**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 19-Apr-2021 21:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-04-2020 14:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-04-2020 14:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-04-2020 14:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 14:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-04-2020 14:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection:  Nov/4/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-04-2020 14:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BPYVBB	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-04-2020 14:38:20 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Jesse LePage	<b>Data Entry:</b> BPYVBB	Initial Entry

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
 Audit Trail History  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1007  
**Site Name:** (1007) Cincinnati Children's Hospital Medical Center  
**Subject No:** 10071443  
**Subject Initials:** ---  
**Generated By:** pfe.levisse  
**Generated Time (GMT):** 19-Apr-2021 21:04

(US & Canada)		(pfe.jlepage)	
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**5.b**

Date	Location	User	Value	Reason
Nov-04-2020 14:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BMRW56	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-04-2020 14:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BMRW56	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-04-2020 14:38:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BMRW57	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-04-2020 14:38:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BMRW57	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071443**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 19-Apr-2021 21:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-04-2020 14:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-04-2020 14:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-04-2020 14:37:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 14:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-04-2020 14:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection:  Nov/4/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-04-2020 14:37:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BPYVB9	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-04-2020 14:37:44 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Jesse LePage	<b>Data Entry:</b> BPYVB9	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

(US & Canada)

(pfe.jlepage)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071443

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Nov-04-2020 14:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-04-2020 14:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-04-2020 14:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-04-2020 14:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> Nov/4/2020 14:14	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-04-2020 14:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Nov-04-2020 14:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> LEFT	Initial Entry

**7. Route:**

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Nov-04-2020 14:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Nov-04-2020 14:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 14:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Nov-04-2020 14:55:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:29:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Nov/25/2020	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1007

Subject No: 10071443

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Date:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Nov/25/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 37.0 <b>Temperature Unit:</b> C <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 37.0	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:40 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

(US & Canada)				
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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 15:58

Site No: 1007

Subject No: 10071443

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Nov/25/2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 09:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 <b>Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Nov-25-2020 09:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071443**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 19-Apr-2021 21:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-25-2020 11:02:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-25-2020 09:29:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-25-2020 09:29:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection:  Nov/25/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-25-2020 11:02:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BP90D7	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-25-2020 11:02:19 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Jesse LePage	<b>Data Entry:</b> BP90D7	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

(US & Canada)

(pfe.jlepage)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071443

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Nov-25-2020 10:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-25-2020 10:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Nov-25-2020 10:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-25-2020 10:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> Nov/25/2020 09:11	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-25-2020 10:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Nov-25-2020 10:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<u>Data Entry:</u> LEFT	Initial Entry

**7. Route:**

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Nov-25-2020 10:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Nov-25-2020 10:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 10:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levissc

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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***1. Date of Visit***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-29-2020 02:11:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Clo sed	Closed per SITE response, added to PD tracker for Clinical Review
Dec-28-2020 08:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Ans wered	protocol deviation was submitted
Dec-23-2020 02:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Op ened	PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 2 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. "[naikp09 SDQ=84993]"
Dec-21-2020 14:20:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry</b> : Dec/2 1/202 0	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071443**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 19-Apr-2021 21:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-21-2020 14:20:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-21-2020 14:20:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-21-2020 15:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-21-2020 14:20:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-21-2020 14:20:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection:  Dec/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-21-2020 15:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BP90ZN	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-21-2020 15:54:49 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Jesse LePage	<b>Data Entry:</b> BP90ZN	Initial Entry

**Header Text:** c4591001  
**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center  
**Subject No:** 10071443 **Subject Initials:** ---  
**Generated By:** pfe.levisse **Generated Time (GMT):** 19-Apr-2021 21:04

(US & Canada)		(pfe.jlepage)	
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**5.b**

Date	Location	User	Value	Reason
Dec-21-2020 15:55:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BMNR2V	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Dec-21-2020 15:55:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BMNR2V	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-21-2020 15:55:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> <b>Sample ID:</b> BMNR2W	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Dec-21-2020 15:55:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jesse LePage (pfe.jlepage)	<b>Data Entry:</b> BMNR2W	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

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

**Form Status:**

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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Date	Location	User	Value	Reason
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071443

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Category:**

Date	Location	User	Value	Reason
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Dec-28-2020 11:48:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 3: Closed	Response satisfies query
Dec-28-2020 08:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 3: Answered	completed on CRF
Dec-15-2020 12:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 3: Reissued:Opened	clinical: Thank you. pls consider adding information regarding MRI findings under causality.
Dec-15-2020 10:52:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 3: Answered	updated relatedness
Dec-13-2020 11:10:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 3: Reissued:Opened	clin: in view of additional info from PI re 'Multiple well-defined rounded foci of non-enhancing increased signal intensity .. within the left medial cerebellar hemisphere' seen on MRI, please review relatedness and update if appropriate.

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<b>Header Text:</b> c4591001 <b>Visit:</b> Logs - Unscheduled <b>Form Version:</b> 22-Apr-2020 21:02 <b>Site No:</b> 1007 <b>Subject No:</b> 10071443 <b>Generated By:</b> pfe.levisse				
<b>Form:</b> ADVERSE EVENT REPORT - eCRF Audit Trail History <b>Form Status:</b> Data Complete, Frozen <b>Site Name:</b> (1007) Cincinnati Children's Hospital Medical Center <b>Subject Initials:</b> --- <b>Generated Time (GMT):</b> 19-Apr-2021 21:04				
Dec-12-2020 09:44:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 3: Answered	Because we don't have alternate etiology we are attributing to vaccine. As participant had no reactogenicity prior to seizure I don't think it is due to the vaccine. However, due to lack of alternative etiology, I think, I have to say event is associated
Dec-09-2020 11:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 3: Opened	clin: confirming: per PI, parents (both MDs) witnessed pt w/ 3 min general tonic clonic sz. Pt completely well for 4 days post vax until this event. She was seen in ED and discharged w/ f/u in sz clinic. In absence of other etiol. PI deems AE 'related'
Dec-09-2020 08:30:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 2: Closed	Response satisfies query
Dec-08-2020 23:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: Answered	subject went to the emergency room
Dec-07-2020 14:17:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 2: Opened	clinical: pls advise where eg ED/clinic and by whom the diagnosis of grand mal seizure was made. Thanks
Dec-03-2020 08:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 1: Closed	Response satisfies query
Dec-02-2020 20:27:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	subject's mother denied any history of seizure
Dec-02-2020 20:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 1: Opened	GPD Clin: please clarify if patient does/does not have

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1007

Subject No: 10071443

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Generated Time (GMT): 19-Apr-2021 21:04

				known seizures at baseline and update medhx terms as appropriate
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Grand Mal Seizure	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Nov/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO End Date Time:  Nov/29/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-05-2020 04:30:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 1: Closed	Response satisfies query
Dec-03-2020 20:06:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	PI does not think this event qualifies as an SAE

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1007**Subject No:** 10071443**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 19-Apr-2021 21:04

Dec-03-2020 08:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 1: Reissued:Opened	GPD Clin:although participant not hospitalized, new onset Grand Mal Seizure could be considered SAE as a Medically Important Event. Please consider submitting SAE report with full narrative for event
Dec-02-2020 20:21:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	subject was not hospitalized
Dec-02-2020 20:08:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 1: Opened	GPD Clin: please confirm that participant did NOT Require hospitalization for the AE grand mal seizure
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-03-2020 08:57:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe mcleol03)	Query 1: Closed	issued on incorrect field
Dec-03-2020 08:53:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe mcleol03)	Query 1: Opened	GPD Clin: Please provide results of evaluation (toxicity screen, head CT/MRI, neurologist evaluation, etc.) when available
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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<b>Header Text:</b> c4591001 <b>Visit:</b> Logs - Unscheduled <b>Form Version:</b> 22-Apr-2020 21:02 <b>Site No:</b> 1007 <b>Subject No:</b> 10071443 <b>Generated By:</b> pfe.levisse				
<b>Form:</b> ADVERSE EVENT REPORT - eCRF Audit Trail History <b>Form Status:</b> Data Complete, Frozen <b>Site Name:</b> (1007) Cincinnati Children's Hospital Medical Center <b>Subject Initials:</b> --- <b>Generated Time (GMT):</b> 19-Apr-2021 21:04				
Dec-17-2020 00:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Usha Ogirala (pfe.ogirau)	Query 4: Closed	Response satisfies query
Dec-16-2020 10:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Dec-16-2020 10:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s) , this event is due to:  OTHER  <i>If Other, specify:</i>  Not related as have additional data now showing relatedness t o other cause	Changed Information
Dec-16-2020 01:20:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 4: Opened	DM: The response for "If Not Related to study treatment(s), this event is due to is reported as "Other", however specify is missing? kindly review and update.
Dec-15-2020 10:46:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s) , this event is due to:  OTHER	New Information
Dec-07-2020 19:49:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 3: Closed	Response satisfies query
Dec-04-2020 12:50:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 3: Answered	there is no alternate etiology at this point so it had to be called related per PI
Dec-03-2020 21:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 2: Closed	Response satisfies query
Dec-03-2020 21:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 3: Opened	ClinQuery: Grand Mal Seizure : please can you confirm why

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1007  
**Subject No:** 10071443  
**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen  
**Site Name:** (1007) Cincinnati Children's Hospital Medical Center  
**Subject Initials:** ---  
**Generated Time (GMT):** 19-Apr-2021 21:04

				the PI felt this AE was related to IP? Thanks
Dec-03-2020 20:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 2: Answered	There were no symptoms that could be associated with COVID or other infection
Dec-03-2020 08:56:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 2: Opened	GPD Clin: Was event accompanied by other symptoms which could be associated with COVID or other infection (URI symptoms, fever, etc.)? Please consider scheduling for COVID illness visit.
Dec-03-2020 08:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 1: Closed	reissuing as modified query
Dec-02-2020 20:09:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 1: Opened	GOD clin: Did participant have an evaluation that ruled other causes for gran mal seizure (EEG/brian scan findings, evaluation for febrile seizures, etc.)?
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> RELATED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Dec-15-2020 20:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 1: Closed	query withdrawn
Dec-11-2020 12:42:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 1: Reissued:Opened	GPD Clin: please update medhx terms to include findings from evaluation or final diagnosis when available (ie. abnormal EEG, intracranial lesions, etc.)
Dec-03-2020 20:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	toxicity screen was not done; will provide results of other evaluations when received
Dec-03-2020 08:58:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 1: Opened	GPD Clin: Please provide results of evaluation (toxicity screen, head CT/MRI, neurologist evaluation, etc.) when available
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-03-2020 21:49:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 1: Closed	Response satisfies query

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Dec-03-2020 14:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	Query 1: Answered	none reported
Dec-02-2020 20:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 1: Opened	GPD Clin: please confirm that no drug or non-drug treatment was given for the AE grand mal seizure
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-01-2020 19:22:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Dec-21-2020 14:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Dec/21/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-21-2020 14:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-21-2020 14:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 19-Apr-2021 21:04

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*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-24-2021 10:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Feb-24-2021 10:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-24-2021 10:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Feb/10/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-24-2021 10:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITI ONAL VACCINATION	Initial Entry



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-24-2021 10:54:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Feb/24/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

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*I. Consent Was:*

Date	Location	User	Value	Reason
Feb-24-2021 10:54:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Feb/24/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION -  
eCRF Audit Trail History

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Feb-24-2021 11:16:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	<b>Data Entry:</b> Feb/24/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-24-2021 11:16:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-24-2021 11:16:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071443

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-24-2021 11:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-24-2021 11:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-24-2021 11:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Feb/24/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 11:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Feb-24-2021 11:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Feb-24-2021 11:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 <b>Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Feb-24-2021 11:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Feb-24-2021 11:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Feb-24-2021 11:51:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071443**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 19-Apr-2021 21:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-24-2021 11:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-24-2021 11:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-24-2021 11:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 11:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-24-2021 11:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES Date of Collection:  Feb/24/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-24-2021 11:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	<b>Data Entry:</b> <b>Sample ID:</b> BR100L	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-24-2021 11:53:13 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Morgan Messeder	<b>Data Entry:</b> BR100L	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 19-Apr-2021 21:04

(US & Canada)		(pfe mmesseder)	
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**5.b**

Date	Location	User	Value	Reason
Feb-24-2021 11:53:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	<b>Data Entry:</b> <b>Sample ID:</b> BSB79L	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-24-2021 11:53:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	<b>Data Entry:</b> BSB79L	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-24-2021 11:53:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	<b>Data Entry:</b> <b>Sample ID:</b> BSB79M	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-24-2021 11:53:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	<b>Data Entry:</b> BSB79M	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071443

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-24-2021 11:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-24-2021 11:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-24-2021 11:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 11:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-24-2021 11:17:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	<b>Data Entry:</b> YES Date of Collection:  Feb/24/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-24-2021 11:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	<b>Data Entry:</b> <b>Sample ID: BR100K</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

Feb-24-2021 11:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Morgan Messeder (pfe mmesseder)	<b>Data Entry:</b> BR100K	Initial Entry
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Header Text: c4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1007

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

Subject No: 10071443

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 19-Apr-2021 21:04

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

Date	Location	User	Value	Reason
Feb-24-2021 11:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-24-2021 11:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-24-2021 11:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-24-2021 11:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Feb/24/2021 11:07	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-24-2021 11:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-24-2021 11:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1007

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

**Subject No:** 10071443

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Feb-24-2021 11:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-24-2021 11:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-24-2021 11:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-24-2021 11:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 11:52:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> YES	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Subject Status**

Date	Location	User	Value	Reason
Dec-21-2020 14:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Nov-04-2020 14:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Nov-04-2020 14:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Dec-21-2020 14:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/21/2020	Initial Entry
Nov-04-2020 14:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/4/2020	Initial Entry
Nov-04-2020 14:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

090177e196d89035\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1007

**Subject No:** 10071443

**Generated By:** pfe.lewissc

**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):** 19-Apr-2021 21:04

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Jan-22-2021 16:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laura Pace (pfe.lpace)	<b>Data Entry:</b> Click Here to Enable	Initial Entry