

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/3/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** DEMOGRAPHY

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10081184]
2.	Birth Date:	(b) (6)1958
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Date of Visit**

1.	Date of Visit	Sep/3/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Sep/3/2020
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:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[High cholesterol]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Thimerosal allergy]
	Start Date:	UNK/UNK/1974
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Elevated PSA]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/3/2020
2.	Weight:	[241.0]
3.	Unit:	LB
4.	Height:	[66.0]
5.	Unit:	in
6.	Body Mass Index:	[38.9]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	FOREHEAD



**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

**Form:** RANDOMIZATION

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/3/2020
2.	Randomization Number:	[251769]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**[eCRF Audit Trail History](#)**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
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	[BPV0LL]
5.b	Sample ID	[BPV0LM]
5.c	Sample ID	[BPV0LN]
5.d	Sample ID	[BRTY0N]
5.e	Sample ID	[BRTY0P]

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
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	[BTPPR1]
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090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/3/2020 14:32
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

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/24/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/24/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.2]
	Unit:	F
	Temperature Location:	FOREHEAD

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/24/2020
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	[BGK140]
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090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/24/2020 10:57
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

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Date of Visit**

1.	Date of Visit	Oct/22/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPZBHL]
5.b	Sample ID	[BRZDFS]
5.c	Sample ID	[BRZDFT]

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**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:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**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:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**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:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**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:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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



**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:** 1008      **Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184      **Subject Initials:** ---

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

**Illness Details**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Unplanned Assessments**

1.	Assessments	
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**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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



**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Prostate cancer	Sep/30/2020 UNK: UNK	YES	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Prostate cancer]
4.	Start Date Time:	Sep/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? NO  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES
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

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[2020412053]

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**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levisse

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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**Medication Error**

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

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flucelvax influenza prophylaxis intramuscular vaccine 0.5 ml once	Oct/19/2020	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flucelvax influenza prophylaxis intramuscular vaccine 0.5 ml once]
5.	Date:	Oct/19/2020

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**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	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:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.	RADIATION THERAPY	1	YES	RADIATION TREATMENT	Feb/22/2021	<a href="#">Repeating Pages</a>

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levisse

**Form:** RADIATION TREATMENT

**Form Status:** Data Complete, Verified

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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**Radiation Treatment**

1.	Category:	RADIATION THERAPY
2.	What is the treatment Identifier?	[1]
3.	Concomitant Non-drug Treatment Pre-specified:	YES
4.	Treatment:	[RADIATION TREATMENT]
5.	Start Date:	Feb/22/2021
6.	Ongoing?	YES

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levisse

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Vital Signs**

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

**Vital Signs Details**

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Contact Outcome**

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

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/11/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Date of Visit**

1.	Date of Visit	Jan/13/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/13/2021
----	--------------	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Jan/13/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/13/2021
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	[BRF5GB]
5.b	Sample ID	[BSCBGH]
5.c	Sample ID	[BSCBGJ]

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/13/2021
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	[BRF5FC]
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090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/13/2021 13:03
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

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/11/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levisse

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**Death Details**

1.	Date of Collection / Notification of Death:	//
----	---	----

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Date of Visit**

1.	Date of Visit	Feb/4/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRG1R4]
-----	-----------	----------

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/4/2021 12:20
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

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**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Date of Visit**

1.	Date of Visit	Mar/4/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/4/2021
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**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:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**Contact Outcome**

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



**Header Text:** c4591001

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

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Mar/4/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/22/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
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**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:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Timothy Jennings	Approved	Mar-10-2021 20:06:42 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-03-2020 13:54:30 (UTC-06:00) Central Time (US & Canada)	Tiffany Baum (pfe.tbaum)	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:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-13-2021 13:14:34 (UTC-06:00) Central Time (US & Canada)	Tiffany Baum (pfe.tbaum)	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:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[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
Timothy Jennings	Approved	Mar-10-2021 20:06:42 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, TimothyJennings, 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.

Tiffany Baum	N/A	Mar-04-2021 11:38:15 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Timothy Jennings	Approved	Feb-21-2021 09:42:07 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TimothyJennings, 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.

Megan Felty	N/A	Feb-04-2021 12:38:16 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Timothy Jennings	Approved	Jan-21-2021 16:30:16 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TimothyJennings, 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.

Tiffany Baum	N/A	Jan-12-2021 13:41:26 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Timothy Jennings	Approved	Nov-03-2020 16:24:09 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TimothyJennings, 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.

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-03-2020 13:53:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:53:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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*I. Consent Was:*

Date	Location	User	Value	Reason
Sep-03-2020 13:54:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1008

Subject No: 10081184

Generated By: pfe.lewissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Sep-03-2020 13:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10081184	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-03-2020 13:53:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1958	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-03-2020 13:54:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-03-2020 13:54:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:54:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-03-2020 13:54:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-03-2020 13:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-03-2020 13:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-03-2020 13:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081184

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

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*1.a*

Date	Location	User	Value	Reason
Sep-03-2020 14:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 1 : <b>Medical History T</b> High choleste <b>erm:</b> rol <b>Start Date:</b> UNK/UNK/2 019 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-03-2020 14:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 14:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> High cholesterol	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Sep-03-2020 14:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

*1.a Ongoing:*

Date	Location	User	Value	Reason
Sep-03-2020 14:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081184

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

**I.b**

Date	Location	User	Value	Reason
Sep-03-2020 14:06:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numbe 2 r: Medical History Thimerosal all Term: ergy Start Date: UNK/UNK/19 74 Ongoing: YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 14:06:58 (UTC-06:00) Central 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
Sep-03-2020 14:06:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Thimerosal allergy	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Sep-03-2020 14:06:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> UNK/UNK/1974	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Sep-03-2020 14:06:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> YES	Initial Entry

**I.c**

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Oct-26-2020 14:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 3 : <b>Medical History Term:</b> Elevated PSA <b>Start Date:</b> UNK/UNK/2019 <b>Ongoing:</b> YES	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1008

Subject No: 10081184

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Oct-26-2020 14:17:01 (UTC-06:00) Central 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-02-2020 13:00:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Nov-02-2020 08:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 1: Answered	No work up prior to enrollment, unknown at this time if benign or stable. Will update term when Prostate cancer is stage.
Nov-01-2020 02:21:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Reissued:Opened	GPDCLIN: Please clarify if any work up was done prior to enrollment to conclude whether benign or stable? please update medical history as applicable or else, please further clarify.
Oct-27-2020 15:04:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 1: Answered	please refer to AE
Oct-27-2020 15:02:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Please clarify the etiology of elevated PSA and if prostate malignancy was ruled out.
Oct-26-2020 14:17:01 (UTC-06:00) Central	ACV0PFEINFP6000	Tiffany Baum	<b>Data Entry:</b> Elevated PSA	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

Time (US & Canada)		(pfe.tbaum)		
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***I.c Start Date:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-26-2020 14:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b><u>Data Entry:</u></b> UNK/UNK/2019	Initial Entry

***I.c Ongoing:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-26-2020 14:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b><u>Data Entry:</u></b> YES	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1008

Subject No: 10081184

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> 241.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> 66.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 38.9	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1008

Subject No: 10081184

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.7 <b>Temperature Unit:</b> F <b>Temperature Location::</b> FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> 97.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 14:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-03-2020 15:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-03-2020 15:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> 251769	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081184**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-03-2020 13:55:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-03-2020 13:55:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-03-2020 15:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 13:55:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 13:55:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> YES Date of Collection:  Sep/3/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-03-2020 15:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrosks)	<b>Data Entry:</b> <b>Sample ID:</b> BPVOLL	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081184

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 15:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<b>Data Entry:</b> BPVOLL	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 15:36:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<b>Data Entry:</b> <b>Sample ID:</b> BPVOLM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 15:36:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<b>Data Entry:</b> BPVOLM	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 15:36:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<b>Data Entry:</b> <b>Sample ID:</b> BPVOLN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 15:36:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<b>Data Entry:</b> BPVOLN	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-03-2020 15:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<b>Data Entry:</b> <b>Sample ID:</b> BRTYON	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.d Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 15:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	<b>Data Entry:</b> BRTYON	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Sep-03-2020 15:36:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	<b>Data Entry:</b> <b>Sample ID:</b> BRTYOP	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 15:36:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	<b>Data Entry:</b> BRTYOP	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081184

Subject Initials: ---

Generated By: pfe.levissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-03-2020 13:55:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-03-2020 13:55:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-03-2020 15:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 13:55:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 13:55:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> YES Date of Collection:  Sep/3/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-03-2020 15:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrosks)	<b>Data Entry:</b> <b>Sample ID: BTPR1</b>	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levisse

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-03-2020 15:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<b>Data Entry:</b> BTPTR1	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081184

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Sep-03-2020 15:37:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-03-2020 15:37:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-03-2020 15:37:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-03-2020 15:37:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Sep/3/2020 14:32	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-03-2020 15:37:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-03-2020 15:37:15 (UTC-06:00) Central	ACV0PFEINFP6000	Tiffany Baum	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

Time (US & Canada)		(pfe.tbaum)	
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**7. Route:**

Date	Location	User	Value	Reason
Sep-03-2020 15:37:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-03-2020 15:37:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 15:37:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-03-2020 13:56:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-24-2020 11:13:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Sep/24/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1008

Subject No: 10081184

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-24-2020 11:13:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Sep/24/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-24-2020 11:13:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.2 <b>Temperature Unit:</b> F <b>Temperature Locati on::</b> FOREHE AD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-24-2020 11:13:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-24-2020 11:13:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> 97.2	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-24-2020 11:13:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levisse

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Sep-24-2020 11:13:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> FOREHEAD	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081184

Subject Initials: ---

Generated By: pfe.levissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-24-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-24-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-24-2020 12:57:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-24-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<b>Data Entry:</b> YES Date of Collection:  Sep/24/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-24-2020 12:57:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<b>Data Entry:</b> Sample ID: BGK140	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-24-2020 12:57:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<b>Data Entry:</b> BGK140	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1008

Subject No: 10081184

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Sep-24-2020 11:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-24-2020 11:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-24-2020 11:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-24-2020 11:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Sep/24/2020 10:57	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-24-2020 11:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-24-2020 11:14:28 (UTC-06:00) Central	ACV0PFEINFP6000	Tiffany Baum	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

Time (US & Canada)		(pfe.tbaum)	
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**7. Route:**

Date	Location	User	Value	Reason
Sep-24-2020 11:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-24-2020 11:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 11:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-22-2020 15:52:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Oct/22/2020	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081184**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-22-2020 15:30:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-22-2020 15:30:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-22-2020 15:31:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 15:30:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-22-2020 15:30:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<b>Data Entry:</b> YES Date of Collection:  Oct/22/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-22-2020 15:31:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooms)	<b>Data Entry:</b> <b>Sample ID:</b> BPZBHL	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081184

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 15:31:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	<b>Data Entry:</b> BPZBHL	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-22-2020 15:31:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	<b>Data Entry:</b> <b>Sample ID:</b> BRZDFS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 15:31:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	<b>Data Entry:</b> BRZDFS	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-22-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	<b>Data Entry:</b> <b>Sample ID:</b> BRZDFT	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 15:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cheyenne Brooks (pfe.cbrooks)	<b>Data Entry:</b> BRZDFT	Initial Entry

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**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

Date	Location	User	Value	Reason
Oct-22-2020 15:53:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Oct/22/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-22-2020 15:53:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-22-2020 15:53:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

**Form Status:**

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081184

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-22-2020 15:58:56 (UTC-06:00) Central 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
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Prostate cancer	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-26-2020 14:43:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	<b>Data Entry:</b> Sep/30/2020 UNK:UNK	Transcription Error
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Oct/7/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081184

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> 2	Initial Entry

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

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Oct-24-2020 08:43:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	Response satisfies query
Oct-23-2020 07:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 2: Answered	SAE was faxed same day
Oct-23-2020 06:30:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:Prostate cancer(Onset date:07Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-23-2020 06:29:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Prostate cancer: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

				Event Number" is blank.
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<p><b>Data Entry:</b> YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**

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

Date	Location	User	Value	Reason
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<p><b>Data Entry:</b> NO</p>	Initial Entry

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

Header Text: c4591001

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Site No: 1008

Subject No: 10081184

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment (s), this event is due to:  OTHER  <i>If Other, specify:</i>  Unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-09-2021 04:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Mar-08-2021 12:50:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	<b>Data Entry:</b> YES	New Information
Mar-08-2021 07:56:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Query 1: Answered	waiting on records to update, as SAE states, records request submitted, they have 90 days to fulfill request, per subject no details at

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

				this time
Mar-07-2021 15:15:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Please confirm subject did not receive any non drug or concomitant drug for his cancer. If yes, please update CRF as applicable and send a FU SAE report. In case a per protocol prohibited therapy was given, please also update PROHIB CM page.
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> NOT RECOVERED/NOT RESO LVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 15:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-24-2020 08:44:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020412053	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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Date	Location	User	Value	Reason
Oct-22-2020 16:00:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081184

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Oct-22-2020 16:00:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-22-2020 16:00:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 16:00:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Oct-23-2020 08:52:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: C losed	Discrepancy has been closed.
Oct-23-2020 07:45:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: A nswered	Transcription Error
Oct-23-2020 07:45:16	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entr y:</b>	Transcription Error

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**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1008  
**Site Name:** (1008) Clinical Research Professionals Inc.  
**Subject No:** 10081184  
**Subject Initials:** ---  
**Generated By:** pfe.levissc  
**Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-06:00) Central Time (US & Canada)			Flucelvax influenza prophylaxis intramuscular vaccine 0.5 ml once	
Oct-23-2020 02:41:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify FLUECELVAX INFLUENZA PROPHYLAXIS INTRAMUSCULAR VACCINE 0.5 ML ONCE as follows...Should the spelling be FLUCELVAX INFLUENZA PROPHYLAXIS INTRAMUSCULAR VACCINE 0.5 ML ONCE? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you.
Oct-22-2020 16:00:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Flucelvax influenza prophylaxis intramuscular vaccine 0.5 ml once	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-22-2020 16:00:25	ACV0PFEINFP6000	Tiffany	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-06:00) Central  
Time (US & Canada)

Baum  
(pfe.tbaum)

Oct/19/2020

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

**Form:** RADIATION TREATMENT - Audit Trail

**Form Status:**

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Mar-08-2021 12:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1008

Subject No: 10081184

Generated By: pfe.levisse

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Mar-08-2021 12:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> RADIATION THERAPY	Initial Entry

**2. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Mar-08-2021 12:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Mar-08-2021 12:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> YES	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Mar-08-2021 12:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> RADIATION TREATMENT	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Mar-08-2021 12:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	<b>Data Entry:</b> Feb/22/2021	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Mar-08-2021 12:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ann Patek (pfe.apatek)	<b>Data Entry:</b> YES	Initial Entry

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**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:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-12-2021 13:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Jan-12-2021 13:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national reco mmendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-13-2021 13:14:16 (UTC-06:00) Central Time (US & Canada)	ACVOPFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF  
Audit Trail History

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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*I. Consent Was:*

Date	Location	User	Value	Reason
Jan-13-2021 13:14:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/13/2021	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:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

Date	Location	User	Value	Reason
Jan-13-2021 13:14:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-13-2021 13:14:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-13-2021 13:14:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (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:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081184**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-13-2021 15:05:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-13-2021 15:05:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-13-2021 15:05:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 15:05:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-13-2021 15:05:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> YES Date of Collection:  Jan/13/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-13-2021 15:05:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> <b>Sample ID:</b> BR55GB	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: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081184

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 15:05:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> BRF5GB	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-13-2021 15:05:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> <b>Sample ID:</b> BSCBGH	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 15:05:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> BSCBGH	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-13-2021 15:05:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> <b>Sample ID:</b> BSCBGJ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 15:05:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> BSCBGJ	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form Version:** 22-Apr-2020 21:03**Site No:** 1008**Subject No:** 10081184**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1008) Clinical Research Professionals Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-13-2021 14:25:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-13-2021 14:25:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-13-2021 14:25:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 14:25:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-13-2021 14:25:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> YES Date of Collection:  Jan/13/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-13-2021 14:25:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> <b>Sample ID:</b> BR5FC	Initial Entry

**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:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-13-2021 14:25:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> BRF5FC	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081184

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Jan-13-2021 14:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-13-2021 14:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-13-2021 14:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-13-2021 14:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Jan/13/2021 13:03	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-13-2021 14:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-13-2021 14:15:15 (UTC-06:00) Central	ACV0PFEINFP6000	Tiffany Baum	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081184

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Time (US & Canada)		(pfe.tbaum)	
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**7. Route:**

Date	Location	User	Value	Reason
Jan-13-2021 14:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-13-2021 14:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-13-2021 14:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-13-2021 14:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 14:15:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-12-2021 13:41:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-12-2021 13:41:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-04-2021 12:57:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Feb/4/2021	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1008

Site Name: (1008) Clinical Research Professionals Inc.

Subject No: 10081184

Subject Initials: ---

Generated By: pfe.levissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-04-2021 12:38:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-04-2021 12:38:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-04-2021 12:39:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 12:38:16 (UTC-06:00) Central 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-04-2021 12:38:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> YES Date of Collection:  Feb/4/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-04-2021 12:39:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> <b>Sample ID: BRG1R4</b>	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-04-2021 12:39:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Megan Felty (pfe.mfelty)	<b>Data Entry:</b> BRG1R4	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081184

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Feb-04-2021 12:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-04-2021 12:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-04-2021 12:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-04-2021 12:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Feb/4/2021 12:20	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-04-2021 12:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-04-2021 12:57:20 (UTC-06:00) Central	ACV0PFEINFP6000	Tiffany Baum	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1008

Subject No: 10081184

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1008) Clinical Research Professionals Inc.

Subject Initials: ---

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

Time (US & Canada)		(pfe.tbaum)	
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**7. Route:**

Date	Location	User	Value	Reason
Feb-04-2021 12:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-04-2021 12:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-04-2021 12:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-04-2021 12:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 12:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-04-2021 11:38:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Mar/4/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

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

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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**1. Contact Type:**

Date	Location	User	Value	Reason
Mar-04-2021 11:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Mar-04-2021 11:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> YES Date of Contact:  Mar/4/2021	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1008**Site Name:** (1008) Clinical Research Professionals Inc.**Subject No:** 10081184**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-05-2021 03:10:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_21
Mar-04-2021 18:15:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7602076;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Mar-04-2021 11:39:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry</b> : Mar/4 /2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-04-2021 11:39:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-04-2021 11:39:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> COMPLETED	Initial Entry



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1008

**Subject No:** 10081184

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject Initials:** ---

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-22-2020 15:53:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-03-2020 15:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-03-2020 13:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-22-2020 15:53:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/22/2020	Initial Entry
Sep-03-2020 15:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/3/2020	Initial Entry
Sep-03-2020 13:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

090177e196ae3fd4\Final\Final On: 01-Apr-2021 05:24 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Site No:** 1008

**Site Name:** (1008) Clinical Research Professionals Inc.

**Subject No:** 10081184

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-22-2020 15:55:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Tiffany Baum (pfe.tbaum)	<b>Data Entry:</b> Click Here to Enable	Initial Entry