

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[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: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/5/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10831050]
2.	Birth Date:	(b) (6)/1941
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/5/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/5/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[penicillin allergy]	
	Start Date:	UNK/UNK/1995	
	Ongoing:	YES	
1.b	Line/MH Number:	[2]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[sulfa allergy]	
	Start Date:	UNK/UNK/1995	
	Ongoing:	YES	
1.c	Line/MH Number:	[3]	Comments
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[iron deficient anemia]	Comments
	Start Date:	UNK/UNK/2015	Comments
	Ongoing:	YES	Comments
1.d	Line/MH Number:	[4]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cataracts]	
	Start Date:	UNK/UNK/2000	
	Ongoing:	NO End Date: UNK/UNK/2000	
1.e	Line/MH Number:	[5]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[glaucoma]	
	Start Date:	UNK/UNK/2008	
	Ongoing:	YES	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

1 f	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	
1.g	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	
1 h	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	
1.i	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	
1.j	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

1 k	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	
1.l	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	
1 m	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	
1 n	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	
1.o	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

1.p	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	
1.q	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	
1.r	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/5/2020
2.	Weight:	[168.6]
3.	Unit:	LB
4.	Height:	[58.0]
5.	Unit:	in
6.	Body Mass Index:	[35.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/5/2020
2.	Randomization Number:	[222881]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/5/2020
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	[BP6V3W]
5.b	Sample ID	[BP6V3X]
5.c	Sample ID	[BP6V3Y]
5.d	Sample ID	[BG1VKK]
5.e	Sample ID	[BG1VKL]

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/5/2020
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	[BP6V45]
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/5/2020 13:49
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

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001	Form: REACTOGENICITY DIARY
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 06-Jul-2020 21:53	Site Name: (1083) Benchmark Research
Site No: 1083	Subject Initials: ---
Subject No: 10831050	Generated Time (GMT): 29-Mar-2021 10:11
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Reactogenicity Diary	
1.	Select appropriate response - Reactogenicity diary collection
YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/3/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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

Lab Urinalysis

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

Lab Result

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

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[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	[BPZ1M9]
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[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 16:27
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5-a	Sample ID	[BPZ1N4]
5-b	Sample ID	[BLCJYS]
5-c	Sample ID	[]

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/28/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Aug/28/2020**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**eCRF Audit Trail History****Signs and Symptoms**

1.	Date of Assessment:	Aug/28/2020
2.	Date of First Symptom Started:	Aug/27/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Sep/2/2020

Symptoms

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

Symptoms - Other

5.a	Symptoms - Other Text:	[Nasal Discharge]
-----	------------------------	-------------------

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1. DELETED	Aug/28/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Aug/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Aug/28/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS COV 2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	INDETERMINATE
8.	Comments/Findings/Details:	[COPAN ITALIA]
9.	Trade Name Other, Specify:	[FLOQswab]

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Site is not seeing a line 4 to enter as requested. This subject did not do a self swab. The subject came in for V2 and prior to visit never recorded any covid related symptoms in diary or to site.]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP6TYF]
-----	-----------	----------

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
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	[BP6TYF]
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Aug/28/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Aug/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Aug/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS	Comments
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO	Comments
3.	Toxicity Grade:	1	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Done _____	Comments
2.	Subcategory of Clinical Event:	Not Done _____	Comments
3.	Was a diagnosis obtained?	Not Done _____	Comments
4.	Toxicity Grade:	Not Done _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Aug/28/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Lab Chemistry Details

1.	Lab Panel:	Not Done _____	Comments
2.	Laboratory Name and Address	Not Done _____ []	Comments
3.	Collection Date:	Not Done _____ //	Comments
4.	Specimen Type:	Not Done _____	Comments

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Aug/28/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.b	Sponsor ID:	Not Done _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Done _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Aug/28/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.d	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

5.e	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Bilirubin_PX21	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Aug/28/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5 f	Sponsor ID:	Not Done _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

5.g	Sponsor ID:	Not Done _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Aug/28/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Laboratory Data Hematology

1.	Lab Panel:	Not Done _____	Comments
2.	Laboratory Name and Address	Not Done _____ []	Comments
3.	Collection Date:	Not Done _____ //	Comments
4.	Specimen Type:	Not Done _____	Comments

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Aug/28/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.b	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Hematocrit_PX2	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

5.c	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Erythrocytes_PX3	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Aug/28/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.d	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Platelets_PX5	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

5.e	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Leukocytes_PX7	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Aug/28/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5 f	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Neutrophils_PX608	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

5.g	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Eosinophils_PX609	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Aug/28/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.h	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Monocytes_PX612	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

5.i	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Basophils_PX610	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Aug/28/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.j	Sponsor ID:	Not Done _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details			Form Instance
1.	Aug/28/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	Not Done	Not Done	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Aug/28/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Vital Signs

1.	Date:	Aug/28/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1	
	Systolic:	Not Done _____ []	Comments
	Diastolic:	Not Done _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Done _____ []	Comments
	Heart Rate in beats/minute:	[75]	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Date:	Vital Signs Details		Form Instance
1.	Aug/28/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	97.0	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Aug/28/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Vital Signs

1.	Date:	Aug/28/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[97.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS
Aug/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Aug/28/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Aug/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Imaging

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____	Comments
4.	Assessment:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Oct/02/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY on Oct/02/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPZ1N4]
5.b	Sample ID	[BLCJYT]
5.c	Sample ID	[BLCJYS]

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Unplanned Assessments

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

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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED	ADVERSE EVENT	1	Cough	Aug/27/2020 00:00	NO End Date Time: Aug/28/2020 00:00	Repeating Pages
2. DELETED	ADVERSE EVENT	2	Shortness of breath	Aug/27/2020 00:00	NO End Date Time: Aug/28/2020 00:00	Repeating Pages
3. DELETED	ADVERSE EVENT	3	Nasal Discharge	Aug/28/2020 00:00	NO End Date Time: Sep/3/2020 00:00	Repeating Pages
4.	ADVERSE EVENT	4	Neck Stiffness	Aug/29/2020 00:00	NO End Date Time: Sep/1/2020 00:00	Repeating Pages
5.	ADVERSE EVENT	5	Scrapping -Bilateral Legs	Sep/30/2020 00:00	YES	Repeating Pages
6.	ADVERSE EVENT	6	Rotator Cuff Separation-Right	Sep/1/2020 00:00	YES	Repeating Pages
7.	ADVERSE EVENT	7	Fall	Sep/1/2020 00:00	NO End Date Time: Sep/1/2020 00:00	Repeating Pages
8.	ADVERSE EVENT	8	Fall	Sep/30/2020 00:00	NO End Date Time: Sep/30/2020 00:00	Repeating Pages
9.	ADVERSE EVENT	9	Brusing-Bilateral Legs	Sep/30/2020 00:00	YES	Repeating Pages

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Cough]
4.	Start Date Time:	Aug/27/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/28/2020 00:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unrelated illness]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Shortness of breath]
4.	Start Date Time:	Aug/27/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/28/2020 00:00
6.	Toxicity Grade:	+
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unrelated illness]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

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

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Nasal Discharge]
4.	Start Date Time:	Aug/28/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/3/2020 00:00
6.	Toxicity Grade:	+
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unrelated illness]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

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

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[4]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Neck Stiffness]	
4.	Start Date Time:	Aug/29/2020 00:00	
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/1/2020 00:00	
6.	Toxicity Grade:	1	
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [ergonomic injury from sleeping wrong]	Comments
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	NO	
12.	Was a Non-Drug Treatment given?	NO	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Scrapping -Bilateral Legs]
4.	Start Date Time:	Sep/30/2020 00:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Injury]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Rotator Cuff Seperation-Right]
4.	Start Date Time:	Sep/1/2020 00:00
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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Orthopedic]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fall]
4.	Start Date Time:	Sep/1/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/1/2020 00:00
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).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Injury]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fall]
4.	Start Date Time:	Sep/30/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/30/2020 00:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Injury]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1083**Subject No:** 10831050**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1083) Benchmark Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[9]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Brusing-Bilateral Legs]
4.	Start Date Time:	Sep/30/2020 00:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Injury]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Medication Error

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

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Concomitant Medications

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

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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?	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Lab Urinalysis

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

Lab Result

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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?	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/25/2021
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

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/26/2021
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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Informed Consent - Further Vaccination

1.	Consent Was:	
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Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Not Started

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Subject Status

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

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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Laurence Chu	Approved	Mar-11-2021 15:46:25 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, LaurenceChu, 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: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-06-2020 16:02:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1.c	Aug-07-2020 13:53:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Permitted Con medications not entered in ecrf but for clarification and query resoslution subject takes oral medication for anemia which does not meet Exc #15

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1.c	Aug-07-2020 13:53:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Permitted Con medications not entered in ecrf but for clarification and query resoslution subject takes oral medication for anemia which does not meet Exc #15

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1.c	Aug-07-2020 13:53:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Permitted Con medications not entered in ecrf but for clarification and query resoslution subject takes oral medication for anemia which does not meet Exc #15

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1.c	Aug-07-2020 13:53:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Permitted Con medications not entered in ecrf but for clarification and query resoslution subject takes oral medication for anemia which does not meet Exc #15

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1	Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2	Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
3	Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4	Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
5	Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4	Oct-12-2020 12:34:45 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Barcodes are listed under the Illnes convalescent visit
			Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-02-2020 12:46:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not done performed in office by PI

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1	Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2	Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
3	Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4	Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
5	Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
6	Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** ILLNESS DETAILS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-29-2020 14:33:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Sep-18-2020 16:06:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1	Sep-29-2020 14:33:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Sep-18-2020 16:06:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2	Sep-29-2020 14:33:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Sep-18-2020 16:06:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
3	Sep-29-2020 14:33:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Sep-18-2020 16:06:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-31-2020 16:52:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1	Aug-31-2020 16:52:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2	Aug-31-2020 16:52:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
3	Aug-31-2020 16:52:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4	Aug-31-2020 16:52:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1	Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
4	Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
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Header Text: c4591001

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Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
5.i	Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
5.j	Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
5.j	Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
5.j	Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
5.j	Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2.a	Aug-31-2020 16:50:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
2.a	Aug-31-2020 16:48:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2.a	Aug-31-2020 16:50:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2.a	Aug-31-2020 16:50:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Instructed by CRA to follow V2 visit and collection further vitals was not a required assessment
			Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-31-2020 16:39:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1	Aug-31-2020 16:39:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2	Aug-31-2020 16:39:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
3	Aug-31-2020 16:39:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-31-2020 16:39:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1	Aug-31-2020 16:39:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2	Aug-31-2020 16:39:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
3	Aug-31-2020 16:39:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4	Aug-31-2020 16:39:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
5	Aug-31-2020 16:39:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
6	Aug-31-2020 16:39:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Aug/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-31-2020 16:39:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Aug-31-2020 16:38:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
1	Aug-31-2020 16:39:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
1	Aug-31-2020 16:38:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
2	Aug-31-2020 16:39:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2	Aug-31-2020 16:38:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Aug/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
3	Aug-31-2020 16:39:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
3	Aug-31-2020 16:38:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
4	Aug-31-2020 16:39:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4	Aug-31-2020 16:38:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Item	Date	User	Comment
9	Sep-10-2020 10:04:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	09SEP2020 PI readvised on "Related" AE and with discussion from work up CRC and PI ruled to Not related and progress notes and AE source will have late entry updates

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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[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
Laurence Chu	Approved	Mar-11-2021 15:46:25 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, LaurenceChu, 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.

(b) (6)	N/A	Feb-10-2021 14:53:39 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Laurence Chu	Approved	Nov-17-2020 10:24:58 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, LaurenceChu, 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.

(b) (6)	N/A	Nov-16-2020 17:08:09 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Laurence Chu	Approved	Nov-06-2020 14:30:20 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (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:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**Affidavit:**

By my dated signature below, I, LaurenceChu, 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.

(b) (6)	N/A	Nov-06-2020 10:48:08 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Laurence Chu	Approved	Oct-21-2020 08:17:11 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, LaurenceChu, 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.

(b) (6)	N/A	Oct-16-2020 09:21:11 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Laurence Chu	Approved	Oct-12-2020 12:43:05 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, LaurenceChu, 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.

(b) (6)	N/A	Oct-12-2020 12:34:45 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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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:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**Affidavit:**

N/A

Laurence Chu	Approved	Oct-09-2020 16:50:05 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, LaurenceChu, 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.

(b) (6)	N/A	Oct-02-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Laurence Chu	Approved	Oct-01-2020 17:46:48 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, LaurenceChu, 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.

(b) (6)	N/A	Sep-29-2020 14:33:30 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Laurence Chu	Approved	Sep-24-2020 11:29:04 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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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:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**Affidavit:**

By my dated signature below, I, LaurenceChu, 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.

(b) (6)	N/A	Sep-23-2020 15:56:20 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Laurence Chu	Approved	Sep-21-2020 12:18:42 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, LaurenceChu, 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.

(b) (6)	N/A	Sep-18-2020 16:05:44 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Laurence Chu	Approved	Sep-14-2020 19:22:11 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, LaurenceChu, 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.

(b) (6)	N/A	Sep-14-2020 16:29:31 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Affidavit:

N/A

Laurence Chu	Approved	Sep-14-2020 12:31:40 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
--------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, LaurenceChu, 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: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-05-2020 14:59:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 14:59:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-05-2020 15:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/5/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-05-2020 14:59:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10831050	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-05-2020 14:59:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1941	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-05-2020 15:01:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-05-2020 15:01:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 15:01:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-05-2020 15:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/5/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-05-2020 15:05:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-05-2020 15:05:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-05-2020 15:05:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1083**Subject No:** 10831050**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1083) Benchmark Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Aug-05-2020 17:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 1 Medical History Term: penicillin allergy Start Date: UNK/UNK/1995 Ongoing: YES	Transcription Error
Aug-05-2020 15:07:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: penicillin allergy - hives Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-05-2020 15:07:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 17:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: penicillin allergy	Transcription Error
Aug-05-2020 15:07:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: penicillin allergy- hives	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-05-2020 15:07:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1995	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-05-2020 15:07:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Aug-06-2020 11:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 2 Medical History Term: sulfa allergy Start Date: UNK/UNK/1995 Ongoing: YES	Changed Information
Aug-05-2020 17:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 2 Medical History Term: sulfa drugs Start Date: UNK/UNK/1995 Ongoing: YES	Transcription Error
Aug-05-2020 15:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: sulfa drugs- hives Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-05-2020 15:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-06-2020 12:55:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-06-2020 11:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-06-2020 11:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sulfa allergy	Changed Information
Aug-05-2020 18:59:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify as follows...Please clarify SULFA DRUGS. Is this a drug allergy, drug reaction, etc? If so, please edit. If reporting administration, transfer to drug. Thank you.
Aug-05-2020 17:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sulfa drugs	Transcription Error
Aug-05-2020 15:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sulfa drugs- hives	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

I.b Start Date:

Date	Location	User	Value	Reason
Aug-05-2020 15:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1995	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-05-2020 15:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-05-2020 17:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 3 Medical History Term: iron deficient anemia Start Date: UNK/UNK/2015 Ongoing: YES	Transcription Error
Aug-05-2020 15:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: iron deficient anemia Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-05-2020 15:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 03:03:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-11-2020 12:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please see line item comment
Aug-11-2020 04:13:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	response not satisfactory. Please review and confirm subject has not taken products listed on exclusion criterion #15? Thanks
Aug-07-2020 13:53:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-06-2020 19:43:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please can you confirm subject has not taken products listed on exclusion criterion #15 as a result of this medhx:iron deficient anemia
Aug-05-2020 17:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> iron deficient anemia	Transcription Error
Aug-05-2020 15:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> iron deficient anemai	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Aug-05-2020 15:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry
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I.c Ongoing:

Date	Location	User	Value	Reason
Aug-05-2020 15:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-05-2020 15:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 4 r: Medical History: cataracts Term: Start Date: UNK/UNK/2000 Ongoing: NO End Date: UNK/UNK/2000	Transcription Error
Aug-05-2020 15:15:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: cataracts rm: Start Date: UNK/UNK/2000 Ongoing: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-05-2020 15:15:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 15:15:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cataracts	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-05-2020 15:15:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-05-2020 15:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2000	Transcription Error
Aug-05-2020 15:15:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-05-2020 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: glaucoma Start Date: UNK/UNK/2008 Ongoing: YES	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-05-2020 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> glaucoma	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-05-2020 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2008	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-05-2020 15:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-05-2020 15:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/5/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-05-2020 15:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 168.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-05-2020 15:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-05-2020 15:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 58.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-05-2020 15:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-05-2020 15:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35.2	Initial Entry

7.a

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Aug-05-2020 15:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.0 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-05-2020 15:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-05-2020 15:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-05-2020 15:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-05-2020 15:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-05-2020 15:12:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-05-2020 15:12:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-05-2020 15:12:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/5/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-05-2020 15:12:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-05-2020 15:12:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-05-2020 15:10:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 Result::	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

			Not Done::	NOT DONE	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-05-2020 15:10:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-05-2020 15:10:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-05-2020 15:10:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-05-2020 15:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/5/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-05-2020 15:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 222881	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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-05-2020 15:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-05-2020 15:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-05-2020 18:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-05-2020 15:12:32 (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.
Aug-05-2020 15:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-05-2020 18:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP6V3W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 18:24:35	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	BP6V3W	
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5.b

Date	Location	User	Value	Reason
Aug-05-2020 18:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP6V3X	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 18:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP6V3X	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-05-2020 18:24:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP6V3Y	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 18:24:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP6V3Y	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-05-2020 19:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BG1VKK	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 19:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BG1VKK	Initial Entry

5.e

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Aug-05-2020 19:09:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BG1VKL	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 19:09:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BG1VKL	Initial Entry

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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-05-2020 15:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-05-2020 15:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-05-2020 18:25:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-05-2020 15:18:13 (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.
Aug-05-2020 15:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-05-2020 18:25:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP6V45	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 18:25:15	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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

(b) (4), (b) (6)

BP6V45

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-05-2020 15:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-05-2020 15:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-05-2020 15:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-05-2020 15:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/5/2020 13:49	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-05-2020 15:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-05-2020 15:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Aug-05-2020 15:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-05-2020 15:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 15:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-15-2020 03:08:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed by DM: (b) (6)
Sep-14-2020 16:29:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Sep-14-2020 16:29:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS SU BJECT	Transcription Error
Sep-13-2020 23:23:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	eDiary RQ: Per Trial Max attributes, subject is the subset of Reactogenicity Diary collection. Please consider updating "Reactogenicity diary collection" as 'Yes'. Else, clarify in query response. Thanks
Sep-12-2020 02:37:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-11-2020 17:06:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	confirmed Vax 2 reactogenicity e-diary was not activated at Visit 2. Deviation noted.
Sep-11-2020 17:03:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Response does not satisfy query
Sep-11-2020 16:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-11-2020 16:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIA RY NOT COLLECTED FOR THI S SUBJECT	Transcription Error

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Sep-09-2020 03:10:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: eCRF unfrozen. Please update as per below query. Thanks
Sep-08-2020 13:11:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Frozen eCRF. Site is unable to update
Sep-07-2020 07:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary RQ: Per Trial Max Attributes, Vaccination eDiary is needed and REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'Yes'. However eDiary records for Vax 2 is not available. Please verify and clarify in query response.
Aug-05-2020 15:20:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS SU BJECT	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-09-2020 03:48:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Sep-08-2020 16:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	OOW due to V2 turned into Covid Illness visit upon Inc/Exc review causing delay
Sep-07-2020 02:55:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed per SITE response
Sep-06-2020 20:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	ClinQuery: V2: Per protocol, vax2 should occur 19-23 days after vax1. Please can you review and confirm a PD will be written as appropriate. Thanks
Sep-04-2020 14:59:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Correct subjects V2 was delayed due to reported Covid Illness reported at V2 that was scheduled 28AUG2020 (SEE COVID ILLNESS VISIT entry) Per PI vaccine had to be delayed to 03SEP2020
Sep-04-2020 04:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	PDQ: Date of visit at this visit is out of window (6 day) from Date of visit (05/Aug/2020) at

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

				VIDIVX1L visit. Please reconcile and update accordingly, else confirm date is correct as is.
Sep-03-2020 19:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_SV001_02
Sep-03-2020 16:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-03-2020 16:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/3/2020	New Information
Sep-03-2020 05:43:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thank you for your response. Form is unfrozen. Please update.
Sep-02-2020 12:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze so site can add Erroneous visit
Sep-02-2020 04:05:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM 1: Thanks for your response. Please mark V2 as erroneous visit.
Aug-31-2020 17:05:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Correct. Marked Erroneous visit. Site is unable to delete the date of visit due to pop up that requires at least the month and year of the visit have been entered.

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Aug-31-2020 04:50:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4391306;The Date of Visit at Visit V2_VAX2_L is the same as the other Date of Visit at Visit COVID_A. Please review for duplication and update as appropriate.
Aug-28-2020 17:08:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT IG UE	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.d

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH ILL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**2.e Symptom:**

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)			Symptom:: NEW OR WORSEN ED MUSC LE PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED MUSCLE P AIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSEN ED JOINT PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.h Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAI N	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the Su bject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN A T INJEC TION SI TE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-03-2020 16:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/3/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-03-2020 16:33:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.9 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:33:07 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)				
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

			Result::	Not Applicable
			Not Done::	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 17:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 17:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 17:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 17:50:36 (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 17:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 17:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZ1M9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 17:50:46	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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

(b) (4), (b) (6) BPZ1M9

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-03-2020 16:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 16:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/3/2020 16:27	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Sep-03-2020 16:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-03-2020 16:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-06-2020 03:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clos ed	Response satisfies query
Oct-05-2020 10:33:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Original value is correct
Oct-05-2020 02:24:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW4878347;The Date of Visit at Visit V3_MONTH1_POSTVAX2_L is the same as the other Date of Visit at Visit COVID_A1. Please review for duplication and update as appropriate.
Oct-02-2020 17:16:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/2/ 2020	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT IG UE	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.d

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH ILL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.e Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)			Symptom:: NEW OR WORSENED MUSCLE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
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2.g Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

2.h Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAI N	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the Su bject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN A T INJEC TION SI TE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 17:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-02-2020 17:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-02-2020 17:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-12-2020 11:53:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-12-2020 11:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Per eCRF guidelines same day V3 and Conv visit. Barcode needed to be recorded in convalescent visit eCRF
Oct-10-2020 04:15:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 10:27:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 10:27:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-09-2020 10:27:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

				Please review and correct as appropriate.
Oct-05-2020 10:33:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-03-2020 05:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-02-2020 17:18:48 (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-02-2020 17:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/2/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-12-2020 12:34:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 10:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZ1N4	Per CCG, If both visits happens on same day. Then the 'sample Collection and Barcode' are to be reported on this visit and in scheduled visit site would need to enter NO to "Sample Collected" and enter a comment. (DELETED)
Oct-05-2020 10:33:35 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZ1N4	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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 10:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZ1N4	Per CCG, If both visits happens on same day. Then the 'sample Collection and Barcode' are to be reported on this visit and in scheduled visit site would need to enter NO to "Sample Collected" and enter a comment. (DELETED)
Oct-07-2020 02:45:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-06-2020 18:03:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-05-2020 14:41:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4891327;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-05-2020 10:33:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZ1N4	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 10:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCJYS	Per CCG, If both visits happens on same day. Then the

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

				'sample Collection and Barcode' are to be reported on this visit and in scheduled visit site would need to enter NO to "Sample Collected" and enter a comment. (DELETED)
Oct-05-2020 10:33:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCJYS	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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.b Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 10:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLCJYS	Per CCG, If both visits happens on same day. Then the 'sample Collection and Barcode' are to be reported on this visit and in scheduled visit site would need to enter NO to "Sample Collected" and enter a comment. (DELETED)
Oct-07-2020 02:45:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-06-2020 18:03:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-05-2020 14:41:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4891325;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-05-2020 10:33:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLCJYS	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-09-2020 10:27:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sample ID:</u>	Per CCG, If both visits happens on same day. Then the 'sample Collection and Barcode' are to be

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

				reported on this visit and in scheduled visit site would need to enter NO to "Sample Collected" and enter a comment. (DELETED)
Oct-09-2020 10:27:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Per CCG, If both visits happens on same day. Then the 'sample Collection and Barcode' are to be reported on this visit and in scheduled visit site would need to enter NO to "Sample Collected" and enter a comment.
Oct-05-2020 10:33:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCJYT	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

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Subject No: 10831050

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.c Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 10:27:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Per CCG, If both visits happens on same day. Then the 'sample Collection and Barcode' are to be reported on this visit and in scheduled visit site would need to enter NO to "Sample Collected" and enter a comment. (DELETED)
Oct-09-2020 10:27:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Per CCG, If both visits happens on same day. Then the 'sample Collection and Barcode' are to be reported on this visit and in scheduled visit site would need to enter NO to "Sample Collected" and enter a comment.
Oct-07-2020 02:45:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-06-2020 18:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-05-2020 14:41:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4891326;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-05-2020 10:33:58 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCJYT	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Central Time (US & Canada)				
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 10:11:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 4: Closed	Will query post clarification.
Oct-13-2020 09:57:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 4: Opened	LIMS Query: As per lab Serum samples with barcodes BLCJYS, BLCJYT, BPZ1N4 is received for V3_MONTH1_POSTVAX2_L. However in InForm is not updated for this visit. Please check and correct the data else submit the SCF for any data change in lab.
Sep-03-2020 19:14:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Closed	Auto closed by Validation Check: VC_SV001_02
Sep-02-2020 13:21:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Frozen V2 eCRF site unable to eat
Sep-02-2020 04:17:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	DM 1: Thanks for your response. Please mark V2 as erroneous visit.
Aug-31-2020 16:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Correct Pt did not report covid related symptoms until proceeding with the Visit 2.

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Aug-31-2020 04:50:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW4391305;The Date of Visit at Visit COVID_A is the same as the other Date of Visit at Visit V2_VAX2_L. Please review for duplication and update as appropriate.
Aug-28-2020 17:23:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Aug-28-2020 17:09:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Aug-28-2020 17:09:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Aug-28-2020 17:09:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Aug/28/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Aug-28-2020 17:09:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-16-2020 09:31:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-16-2020 09:21:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-15-2020 03:13:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Oct-12-2020 13:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Aug-28-2020 17:15:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020**Form Version:** 21-Aug-2020 02:52**Site No:** 1083**Subject No:** 10831050**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1083) Benchmark Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

Nov-16-2020 17:08:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Sep/2/2020	New Information
Oct-16-2020 09:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Sep/1/2020	New Information
Sep-23-2020 16:12:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 15:56:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Sep-23-2020 14:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, subject reported nasal discharge. Please add under "Other"
Aug-28-2020 17:15:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

4.b

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

4.c Symptoms:

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**4.e Symptoms:**

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

4.g Symptoms:

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**4.i Symptoms:**

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Aug-28-2020 17:13:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 15:56:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other Nasal Discharge	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-16-2020 17:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 17:08:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-16-2020 16:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per AE log, nasal discharge ended on 02Sep2020. Please update last day of symptoms date.
Sep-23-2020 15:56:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nasal Discharge	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
Aug/28/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-02-2020 12:58:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Not done- Entered in error. Only a SWAB performed by PI was performed at this visit. Per CRC follow V2 schedule of events. Subject did not use a sponsor provided at home swab or have a SWAb tested anywhere else.
Aug-28-2020 17:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Aug-28-2020 17:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Aug-28-2020 17:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Aug-28-2020 17:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Aug-28-2020 17:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Aug-28-2020 17:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Sep-02-2020 23:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Sep-02-2020 12:58:30	ACV0PFEINFP6000	auto query	Query 1: Answered	Not done- Entered in

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Deleted, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11***** THIS REPEATING FORM HAS BEEN DELETED *****

(UTC-06:00) Central Time (US & Canada)		(autoquery)		error. Only a SWAB performed by PI was performed at this visit. Per CRC follow V2 schedule of events. Subject did not use a sponsor provided at home swab or have a SWAb tested anywhere else.
Sep-02-2020 09:31:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per CRF CRs section 8.29.7. please include the manufacturer and SARS Cov-2 test kit name. FLOQswab is a COVID-19 Sample Collection Kit not a SARS Cov-2 test.
Aug-28-2020 17:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Aug-28-2020 17:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: INDETERMINATE	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Sep-02-2020 12:50:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-02-2020 12:50:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COPAN ITALIA	Transcription Error
Sep-02-2020 12:49:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Copan ITALIA SpA	Transcription Error
Sep-02-2020 12:49:01	ACV0PFEINFP6000	auto query	Query 1: Opened	Entered text has either

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

(UTC-06:00) Central Time (US & Canada)		(autoquery)		a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Sep-02-2020 12:49:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COPAN ITALIA SpA	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Sep-01-2020 08:57:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Need to discuss with CDS.
Aug-31-2020 16:29:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Used sponsor provided swab
Aug-31-2020 07:10:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM : Trade Name does not match uniquely with an approved Covid Test Trade Name. Please confirm and update else clarify.
Aug-28-2020 17:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FLOQ _{swab}	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-02-2020 13:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry
Sep-02-2020 12:46:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Aug-31-2020 17:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry
Aug-31-2020 16:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Aug-28-2020 17:23:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-02-2020 13:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB_SELF	Initial Entry
Sep-02-2020 12:46:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Aug-31-2020 17:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB_SELF	Initial Entry
Aug-31-2020 16:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Aug-28-2020 17:23:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1083**Subject No:** 10831050**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1083) Benchmark Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

Date	Location	User	Value	Reason
Sep-07-2020 05:49:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Closing query as reason for sample not collected entered.
Sep-04-2020 14:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Answer Auto Query
Sep-03-2020 14:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	DM Re-query: Please provide a reason on line 4 why sample was not collected.
Sep-02-2020 13:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Subject seen for V2. Prior to V2 subject had not reported covid related symptoms. During reconfirmation of eligibility subject reported potential COVID 19 illness symptoms that did meet the criteria for temporarily delaying study intervention
Sep-02-2020 13:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Sep-02-2020 13:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Sep-02-2020 12:46:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Sep-02-2020 12:46:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

Header Text: c4591001 Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form Version: 22-Apr-2020 21:03 Site No: 1083 Subject No: 10831050 Generated By: (b) (4)					Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History Form Status: Data Complete, Frozen, Verified Site Name: (1083) Benchmark Research Subject Initials: --- Generated Time (GMT): 29-Mar-2021 10:11				
Sep-02-2020 02:06:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.					
Sep-01-2020 17:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.					
Aug-31-2020 17:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query					
Aug-31-2020 17:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.					
Aug-31-2020 17:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry					
Aug-31-2020 16:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query					
Aug-31-2020 16:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error					
Aug-31-2020 00:13:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.					
Aug-28-2020 17:23:34 (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.					
Aug-28-2020 17:23:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry					

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1083**Subject No:** 10831050**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1083) Benchmark Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11

Aug/28/2020

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Sep-04-2020 14:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-04-2020 14:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Site is not seeing a line 4 to enter as requested. This subject did not do a self swab. The subject came in for V2 and prior to visit never recorded any covid related symptoms in diary or to site.	Transcription Error
Sep-04-2020 14:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Sep-04-2020 14:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Site is not seeing a line 4 to enter as requested. This subject did not do a self swab. The subject came in for V2 and prior to visit never recorded any covid related symptoms in diary or to site.	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 17:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP6TYF	Transcription Error (DELETED)
Aug-31-2020 17:02:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP6TYF	Transcription Error
Aug-31-2020 17:02:16 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: bp6tyf	Transcription Error

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)				
Aug-31-2020 17:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP6TYF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 01:42:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Closed by DM: (b) (6)
Sep-03-2020 02:09:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed by DM: (b) (6)
Sep-02-2020 14:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ecrf has been deleted and was not done
Sep-02-2020 13:38:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Subject came in for V2. Prior to V2 visit subject had not reported covid related symptoms. During reconfirmation of eligibility subject reported potential COVID 19 illness symptoms that did meet the criteria for temporarily delaying study intervention adm
Sep-02-2020 07:11:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Closing as barcode entry is deleted and other query opened for sample ID entry
Sep-02-2020 04:08:42	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued: Opened	DM 1: Thanks for your response. Since

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001				
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020		Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History		
Form Version: 22-Apr-2020 21:03		Form Status: Data Complete, Frozen, Verified		
Site No: 1083		Site Name: (1083) Benchmark Research		
Subject No: 10831050		Subject Initials: ---		
Generated By: (b) (4)		Generated Time (GMT): 29-Mar-2021 10:11		
(UTC-06:00) Central Time (US & Canada)			d	"Sample collected" is "Yes", barcode should be present. Please review and correct as appropriate.
Sep-02-2020 02:46:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM 1: Thanks for your response. Barcode length does not have 7 characters. Since "Sample collected" is "Yes", barcode should be present. Please review and correct as appropriate.
Sep-01-2020 17:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP6TYF	Transcription Error (DELETED)
Sep-01-2020 17:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error
Sep-01-2020 17:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Sep-01-2020 05:18:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 4: Opened	DMW4427402;This Barcode BP6TYF appears to be already recorded within the study for same subject. Please review and update as appropriate.
Aug-31-2020 19:29:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW4427367;This Barcode is already recorded more than once (for the same subject). Please

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

				review and update as appropriate.
Aug-31-2020 17:03:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Query is ambiguous
Aug-31-2020 17:02:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-31-2020 17:02:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP6TYF	Transcription Error
Aug-31-2020 17:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Barcode contains lower case letters which is not the correct format. Please review and correct as appropriate.
Aug-31-2020 17:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bp6tyf	Transcription Error
Aug-31-2020 17:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 7 characters in length. Please review and correct as appropriate.
Aug-31-2020 17:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP6TYF	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-28-2020 17:31:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 17:31:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-28-2020 18:00:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 17:31:35 (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.
Aug-28-2020 17:31:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 18:00:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP6TYF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY	Query 1: CI	Auto closed by

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

19:33:44 (UTC-06:00) Central Time (US & Canada)		(b) (4)	osed	Validation Check: VC_BEETRK001_01
Sep-01-2020 17:01:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swered	Original value is correct
Aug-31-2020 19:29:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW4427366;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Aug-28-2020 18:00:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP6TYF	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Aug-28-2020 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts: NO	Initial Entry
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Aug-28-2020 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Aug-28-2020 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENC Y ROOM Occurrence of Visits or Contacts: NO	Initial Entry
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENC Y ROOM Occurrence of Visits or Contacts:	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Aug-28-2020 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-28-2020 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts:	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Aug-28-2020 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Aug-28-2020 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts:	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Aug-28-2020 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-28-2020 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts:	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11***I.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Aug-28-2020 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-28-2020 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Co ntacts: NO	Initial Entry
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Co ntacts:	Initial Entry

I.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

I.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Aug-28-2020 17:26:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

Nov-06-2020 14:38:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 10:48:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-06-2020 10:48:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-06-2020 02:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Opened	Other Type of Practitioner Specify” is expected to be completed only when the “Type of Practitioner” is OTHER and response for “Occurrence of Visits or Contacts” is answered as Yes. Hence, please verify and remove the specification comment if not relevant
Aug-28-2020 17:26:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: subject did not seek med attention	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 05:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed by DM: (b) (6)
Aug-28-2020 17:34:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no other med attention
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	There are no visits or contacts reported and subject has not been hospitalized, please confirm whether the participant sought medical attention for

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

				this respiratory illness episode. If not, please correct data.
Aug-28-2020 17:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Aug-28-2020 17:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-08-2020 17:06:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-08-2020 16:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-08-2020 16:08:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM QUERY: As subject is symptomatic, per CCG's toxicity grade from 1-5 should be entered. Please update.
Oct-08-2020 16:08:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Issued in error.
Oct-08-2020 16:07:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Toxicity grade needs to be entered.
Oct-08-2020 07:30:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLIQUEY: As subject is symptomatic, per CCG's toxicity grade from 1-5 should be entered. Please update.
Sep-29-2020 14:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry
Sep-29-2020 14:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Sep-18-2020 16:06:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Sep-18-2020 16:05:55 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	New Information

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)				
Aug-28-2020 17:28:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-05-2020 01:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query
Sep-29-2020 14:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-29-2020 14:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Sep-29-2020 14:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 02:33:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: per CCG, this form is a required CRF, please complete as appropriate. if Diagnosis is not obtained, answer the question as "NO" and enter toxicity grade between 1-5 as per CCG section 8.13.5 as it relates to Symptoms.
Sep-18-2020 16:06:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-18-2020 16:05:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Aug-28-2020 17:28:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-08-2020 16:58:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	New Information
Sep-29-2020 14:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0	Initial Entry
Sep-29-2020 14:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-20-2020 23:27:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query
Sep-18-2020 16:06:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Sep-18-2020 16:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-18-2020 16:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	New Information
Sep-17-2020 00:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLIQUEY: Thank you for your response. Per CCG, section 8.31.5, toxicity grade between 1-5 is expected as it relates to the symptoms reported in the SOD CRF within this visit. Toxicity grade is not dependent on diagnosis. please update as appropriate.
Sep-17-2020 00:50:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Reissued:Candidate	CLIQUEY: Thank you for your response. Per CCG, section 8.31.5, toxicity grade between 1-5 is expected as it relates

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

				to the symptoms reported in the SOD CRF within this visit. Toxicity grade is not dependent on diagnosis. please update as appropriate.
Sep-15-2020 15:45:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Original value is correct
Sep-15-2020 05:31:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	Clinical Query: per CRF CR guidelines section 8.31.5, please select appropriate toxicity grade between 1-5 as it relates to the symptoms reported in the SOD form.
Aug-31-2020 17:00:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 0	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Aug-31-2020 16:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Aug-31-2020 16:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Aug-31-2020 16:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-31-2020 16:52:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.b Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Sponsor-Defined Identifi Not Don	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)			er:	e	
			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

5.c Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Subject No: 10831050

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Generated Time (GMT): 29-Mar-2021 10:11

5.d

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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5.d LNMT

Date	Location	User	Value	Reason
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5.e

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

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Form Version: 30-Jul-2020 21:27

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			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.e Sponsor ID:

Date	Location	User	Value	Reason
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5.f

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Sponsor-Defined Identifi Not Don	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

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Form Version: 30-Jul-2020 21:27

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Generated Time (GMT): 29-Mar-2021 10:11

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			Test:: Not Done	
			Result:: Not Done	
			Not Done:: Not Done	
			Lab Normal Range: Not Done	

5.f Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Date	Location	User	Value	Reason
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Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Generated Time (GMT): 29-Mar-2021 10:11

5.g

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.g Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Aug-31-2020 16:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

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Site No: 1083

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5.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

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5.c

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifi Not Don	Initial Entry

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			Test::	Not Done	
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			Result::	Not Done	
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			Lab Normal Range:	Not Done	
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Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifi Not Don	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)			er:	e	
			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

5.f Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form Version: 30-Jul-2020 21:28

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

5.g

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.h Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifi Not Don	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form Version: 30-Jul-2020 21:28

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)			er:	e	
			Test::	Not Don	
				e	
			Result::	Not Don	
				e	
			Not Done::	Not Don	
				e	
			Lab Normal Range:	Not Don	
				e	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

5.i Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.j Sponsor ID:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Aug-31-2020 16:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Audit Trail
Aug/28/2020

Form Version: 30-Jul-2020 21:27

Form Status:

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Aug-28-2020 17:31:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Date:

Date	Location	User	Value	Reason
Sep-01-2020 07:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closing as fields marked Not Done with comment
Aug-31-2020 16:48:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry
Aug-31-2020 16:29:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-31-2020 16:29:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-31-2020 01:57:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: In the Vital sign form, the response for systolic, diastolic and heart rate is missing? kindly review and update.
Aug-28-2020 17:31:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-31-2020 16:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: Not D one Diastolic:: Not D one Respiratory Rate in respir Not D ations/minute: one Heart Rate in beats/minute 75 :	Initial Entry
Aug-31-2020 16:50:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified
Site No: 1083 **Site Name:** (1083) Benchmark Research
Subject No: 10831050 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:11

			Systolic:: Not D one Diastolic:: Not D one Respiratory Rate in respir ations/minute: Heart Rate in beats/minute 75 :	
Aug-31-2020 16:48:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: Not D one Diastolic:: Respiratory Rate in respir ations/minute: Heart Rate in beats/minute 75 :	Initial Entry
Aug-31-2020 16:48:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: Diastolic:: Respiratory Rate in respiration s/minute: Heart Rate in beats/minute: 7 5	Initial Entry
Aug-28-2020 17:31:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: Diastolic:: Respiratory Rate in respirations /minute: Heart Rate in beats/minute:	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 17:31:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Aug-31-2020 16:48:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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2.a Diastolic:

Date	Location	User	Value	Reason
Aug-31-2020 16:50:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Aug-31-2020 16:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Aug-31-2020 16:48:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 75	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
Aug/28/2020

Form Version: 30-Jul-2020 21:28

Form Status:

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Aug-31-2020 16:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-31-2020 16:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 97.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 16:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Aug-31-2020 16:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.0	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date Time of Assessment:

Date	Location	User	Value	Reason
Aug-31-2020 16:39:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Aug-31-2020 16:39:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Aug-31-2020 16:39:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Aug-31-2020 16:39:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Aug-31-2020 16:39:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Aug-31-2020 16:39:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	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
Aug-31-2020 16:39:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 16:39:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Aug-31-2020 16:39:38 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/28/2020 Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Aug-31-2020 16:39:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Aug-31-2020 16:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Aug-31-2020 16:39:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Aug-31-2020 16:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Aug-31-2020 16:39:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Aug-31-2020 16:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Aug-31-2020 16:39:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Aug-31-2020 16:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail on Oct/02/2020**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Oct-06-2020 03:27:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-05-2020 10:50:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Original value is correct
Oct-05-2020 02:24:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW4878346;The Date of Visit at Visit COVID_A1 is the same as the other Date of Visit at Visit V3_MONTH1_POSTVAX2_L. Please review for duplication and update as appropriate.
Oct-02-2020 17:19:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Oct/2/ 2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-02-2020 17:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Oct/02/2020 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-02-2020 17:20:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-02-2020 17:20:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 12:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-09-2020 08:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Oct-09-2020 01:58:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Per CCG, If both visits happens on same day. Then the 'sample Collection and Barcode' are to be reported on this visit and in scheduled visit site would need to enter NO to "Sample Collected" and enter a comment.
Oct-08-2020 11:34:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Please see V3 same day visit as Potential Covid Illness Barcodes are entered there
Oct-07-2020 08:24:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	'Sample Collected?' is Yes, however no barcodes are entered.

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Header Text: c4591001
Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF on Oct/02/2020
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1083 **Site Name:** (1083) Benchmark Research
Subject No: 10831050 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:11

				Please review and correct as appropriate.
Oct-06-2020 18:02:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-05-2020 10:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-03-2020 05:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-02-2020 17:20:11 (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-02-2020 17:20:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 08:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZ1N4	Transcription Error
Oct-06-2020 18:01:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZ1N4	New Information (DELETED)
Oct-05-2020 10:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPZ1N4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

Header Text: c4591001
Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
 on Oct/02/2020 Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1083 **Site Name:** (1083) Benchmark Research
Subject No: 10831050 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:11

08:26:46 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	BPZ1N4	
Oct-07-2020 00:47:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-06-2020 18:01:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZ1N4	New Information (DELETED)
Oct-06-2020 18:01:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-05-2020 14:41:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4891324;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-05-2020 10:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPZ1N4	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 08:33:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCJYT	Transcription Error
Oct-09-2020 08:31:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: blcjyt/	Initial Entry
Oct-09-2020 08:27:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit
on Oct/02/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Oct-06-2020 18:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error (DELETED)
Oct-06-2020 18:01:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Oct-05-2020 10:54:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLCJYS	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Oct/02/2020 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.b Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 20:51:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 4: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-09-2020 15:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Original value is correct
Oct-09-2020 14:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 4: Opened	DMW4937025;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-09-2020 08:33:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-09-2020 08:33:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-09-2020 08:33:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCJYT	Transcription Error
Oct-09-2020 08:31:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Oct-09-2020 08:31:58 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Barcode contains lower case letters which is not the correct format. Please

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Oct/02/2020 Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

(US & Canada)				review and correct as appropriate.
Oct-09-2020 08:31:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: blcjyt/	Initial Entry
Oct-09-2020 08:27:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-07-2020 07:47:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-06-2020 18:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error (DELETED)
Oct-06-2020 18:01:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-06-2020 18:01:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-05-2020 14:41:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4891282;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-05-2020 10:54:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCJYS	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Oct/02/2020 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.c

Date	Location	User	Value	Reason
Oct-09-2020 15:25:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BLCJYS	New Information
Oct-09-2020 08:29:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BLCJYT	Transcription Error
Oct-06-2020 18:02:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BLCJYT	Transcription Error (DELETED)
Oct-05-2020 10:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BLCJYT	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Oct/02/2020 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

5.c Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 20:51:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-09-2020 15:25:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Oct-09-2020 15:25:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCJYS	New Information
Oct-09-2020 14:43:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW4937026;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-09-2020 08:29:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCJYT	Transcription Error
Oct-07-2020 07:47:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-06-2020 18:02:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCJYT	Transcription Error (DELETED)
Oct-06-2020 18:02:34 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Oct/02/2020 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

(US & Canada)				
Oct-05-2020 14:41:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4891323;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-05-2020 10:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLCJYT	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-05-2020 11:25:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/2/2020	New Information
Oct-02-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-02-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-02-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COMPLETED	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-10-2020 10:10:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Per PA5-Section 8.3.7. this AE to be deleted as this event is already documented on the COVID Illness CRF SOD form and should be removed from the AE CRF form
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-10-2020 10:12:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Per PA5-Section 8.3.7. this AE to be deleted as this event is already documented on the COVID Illness CRF SOD form and should be removed from the AE CRF form
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-10-2020 10:13:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Per PA5-Section 8.3.7. this AE to be deleted as this event is already documented on the COVID Illness CRF SOD form and should be removed from the AE CRF form
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-13-2020 20:06:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Sep-10-2020 10:10:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Per PA5-Section 8.3.7. this AE to be deleted as this event is already documented on the COVID Illness CRF SOD form and should be removed from the AE CRF form
Sep-08-2020 16:28:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Per PA5-Section 8.3.7., please this event is already documented on the COVID Illness CRF SOD form and should be removed from the AE CRF form.
Sep-08-2020 16:09:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	These were recorded as AE's per PI. The subject did not report on ed diary and did not contact site prior to v2.

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

Sep-07-2020 12:26:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per PA5-Section 8.3.7., COVID-19 related event does not qualify as AE and please should be documented only on the COVID Illness CRF SOD form and should not be captured on the AE CRF form.
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cough	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/28/2020 00:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-03-2020 16:53:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Unrelated illness	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

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

Date	Location	User	Value	Reason
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-13-2020 20:06:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Sep-10-2020 10:12:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Per PA5-Section 8.3.7. this AE to be deleted as this event is already documented on the COVID Illness CRF SOD form and should be removed from the AE CRF form
Sep-08-2020 16:29:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Per PA5-Section 8.3.7., please this event is already documented on the COVID Illness CRF SOD form and should be removed from the AE CRF form.
Sep-08-2020 16:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	These were recorded as AE's per PI. The subject did not report on ed diary and did not contact site prior to

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

				v2.
Sep-07-2020 12:26:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per PA5-Section 8.3.7., COVID-19 related event does not qualify as AE and please should be documented only on the COVID Illness CRF SOD form and should not be captured on the AE CRF form.
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Shortness of breath	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/27/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/28/2020 00:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Unrelated illness	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	NO	
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-13-2020 20:06:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Sep-10-2020 10:13:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Per PA5-Section 8.3.7. this AE to be deleted as this event is already documented on the COVID Illness CRF SOD form and should be removed from the AE CRF form
Sep-08-2020 16:32:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Per PA5-Section 8.3.7., please this event should be documented/added on the COVID Illness CRF SOD form "Symptoms Other" and should be removed from the AE CRF form.
Sep-08-2020 16:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	These were recorded as AE's per PI. The subject did not report on ed diary and did not

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

				contact site prior to v2.
Sep-07-2020 12:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: The subject experienced "Nasal Discharge" on 28AUG2020. Per PA5-Sections 8.1., 8.3.7, 8.13., please this symptom should be added to the COVID Illness Visit CRF SOD form.
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nasal Discharge	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/28/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/3/2020 00:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-07-2020 04:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed by DM: (b) (6)
Sep-04-2020 15:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-04-2020 15:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Sep-04-2020 07:56:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: In adverse Event form the response for "Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log." is missing, kindly review and update.

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Unrelated illness	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:52:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neck Stiffness	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/29/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/1/2020 00:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-13-2020 17:36:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-10-2020 10:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-10-2020 10:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER If Other, specify: ergonomic injury from sleepin g wrong	New Information
Sep-09-2020 19:12:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery: response not satisfactory. why does the PI feel this is related to IP? The AE began pre vaccination. thanks

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Sep-08-2020 16:16:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	CRC will have PI assess and will update with a line item comment
Sep-06-2020 20:35:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Neck Stiffness: please can you advise why the PI feels this is related to vaccine as it began 4 days before V2? Thanks
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Sep-03-2020 16:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-08-2020 13:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Oct-08-2020 11:29:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-08-2020 11:29:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Scrapping -Bilateral Legs	New Information
Oct-07-2020 17:01:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple actions for SCRAPPING AND BRUISING- BILATERAL LEGS: Split the term into SCRAPPING BILATERAL LEGS and BRUISING-

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

				BILATERAL LEGS and report as separate entries and also clarify SCRAPPING BILATERAL LEGS whether reporting SCRAPPING (ABRASION) BILATERAL LEGS or other and update the term as appropriate. Thank you.
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Scrapping and Bruising-Bilateral Legs	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Injury	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 13:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Rotator Cuff Separation-Right	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Orthopedic	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 13:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fall	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/1/2020 00:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Injury	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1083**Subject No:** 10831050**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1083) Benchmark Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fall	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/30/2020 00:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Injury	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 13:48:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Brusing-Bilateral Legs	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Injury	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 11:32:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-10-2021 14:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/25/2021	Initial Entry

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

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

Date	Location	User	Value	Reason
Mar-13-2021 02:17:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Please update as per query response provided when data is available.
Mar-12-2021 09:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	We finally got an update regarding this subject she is currently in the hospital. Confirmed non-covid related and secondary to an old bariatric surgery complication. Site has already requested records for diagnosis and SAE Completion.
Mar-12-2021 05:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM1: Thank you for the response, however V101 visit is not updated yet, kindly confirm the status of the visit.
Mar-10-2021 10:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	visit rescheduled 11MAR2021
Mar-09-2021 23:58:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Site has made multiple attempts to contact subject to reschedule tentatively rescheduled 11MAR2021
Mar-09-2021 10:12:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM RQ: Please consider if the participant is lost to follow-up. If yes, please update the DISP FUP form. Else, clarify.
Mar-08-2021 20:58:00	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject was scheduled

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:25**Form Status:** Data Complete**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		for OOW V101 on 06MAR2021 and subject did not show up to appointment. Site has been leaving messages for subject to call back to reschedule
Mar-05-2021 06:41:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Participant is eligible and confirmed to have received Placebo, but Date Written Consent Obtained is missing in Informed Consent - Further Vaccination CRF. Please review and update as appropriate.
Feb-10-2021 14:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 14:54:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-10-2021 14:54:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-10-2021 14:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-10-2021 14:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDI TIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831050

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-02-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-05-2020 15:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-05-2020 15:05:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-05-2020 11:25:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/2/2020	New Information
Oct-02-2020 17:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry
Aug-05-2020 15:12:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/5/2020	Initial Entry
Aug-05-2020 15:05:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/5/2020	Initial Entry

090177e196ae3f93\Final\Final On: 01-Apr-2021 05:19 (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: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Sep-14-2020 11:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry