

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**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:** 10831060

**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/6/2020
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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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10831060]
2.	Birth Date:	(b) (6)/1975
3.	Sex:	MALE
4.	Ethnicity:	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:** 10831060

**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/6/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**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:** 10831060

**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/6/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergic Rhinitis-Seasonal]
	Start Date:	UNK/UNK/1976
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Umbilical hernia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Partial Achilles Tendon Tear-Right Foot]
	Start Date:	Mar/UNK/2018
	Ongoing:	NO End Date: Mar/UNK/2018
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hair Loss]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

090177e196ae3f94\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:** 10831060**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.e	Line/MH Number:	[5]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Pectoralis Tendon Tear-Right]	
	Start Date:	UNK/UNK/2013	
	Ongoing:	NO End Date: UNK/UNK/2013	
1.f	Line/MH Number:	[6]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Right Foot Achilles Tendon Repair]	
	Start Date:	Mar/UNK/2018	
	Ongoing:	NO End Date: Mar/UNK/2018	
1.g	Line/MH Number:	[7]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Pectoralis tendon Tear Repair-Right]	
	Start Date:	UNK/UNK/2013	
	Ongoing:	NO End Date: UNK/UNK/2013	
1.h	Line/MH Number:	[8]	<a href="#">Comments</a>
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Stomach Cramps]	<a href="#">Comments</a>
	Start Date:	Aug/3/2020	<a href="#">Comments</a>
	Ongoing:	YES	<a href="#">Comments</a>



**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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/6/2020
2.	Weight:	[180.2]
3.	Unit:	LB
4.	Height:	[68.0]
5.	Unit:	in
6.	Body Mass Index:	[27.4]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**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/6/2020
2.	Randomization Number:	[43386]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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: Aug/6/2020
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	[BP6V56]
5.b	Sample ID	[BP6V57]
5.c	Sample ID	[BP6V58]
5.d	Sample ID	[BG1VL5]
5.e	Sample ID	[BG1VL6]
5.f	Sample ID	[ ]
5.g	Sample ID	[BP6V4H]

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**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**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/6/2020
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	[BP6V4F]
5.b	Sample ID	[BP6V4H]

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**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**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/6/2020 11:30
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

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**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**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](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1083

**Subject No:** 10831060

**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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Not Applicable _____ //	<a href="#">Comments</a>
2.	Erroneous Visit	Not Applicable _____	<a href="#">Comments</a>

**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, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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?	YES Ongoing? NO Stop Date: Aug/13/2020
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/13/2020
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/13/2020
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3f94\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, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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
2.h	Symptom:	NEW OR WORSENERED 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

090177e196ae3f94\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, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Not Started

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

**Vital Signs**

1.	Date:	//
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**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

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

**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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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Not Started

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

**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?	

090177e196ae3f94\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:** 10831060

**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/22/2020
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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Form Comments](#)

[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?	Not Applicable _____	<a href="#">Comments</a>
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable _____	<a href="#">Comments</a>
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable _____	<a href="#">Comments</a>
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable _____	<a href="#">Comments</a>
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable _____	<a href="#">Comments</a>
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3f94\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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

2 f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2 h	Symptom:	NEW OR WORSENERD JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
3.	Injection Site Location:	Not Applicable	<a href="#">Comments</a>
4.	Injection Site Body Side:	Not Applicable	<a href="#">Comments</a>
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>

090177e196ae3f94\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, Frozen, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP21WJ]
5.b	Sample ID	[BPHMT3]
5.c	Sample ID	[BPHMT4]

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**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	Dec/4/2020
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 Dec/04/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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:	Dec/4/2020
2.	Date of First Symptom Started:	Dec/2/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Dec/17/2020

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	YES
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
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?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

**Symptoms - Other**

5.a	Symptoms - Other Text:	[Runny Nose]
-----	------------------------	--------------

**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:** 10831060

**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.	Dec/2/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Dec/2/2020
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:	POSITIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[SARS-CoV-2 RNA CLIA CERTIFIED LAB]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**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_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Self Swab not done but performed by PI]

**Aliquot**

Please enter barcode for each aliquot.

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**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: Dec/4/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BKN286]
-----	-----------	----------

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**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:	YES Number of Visits or Contacts: [1]

**Health Care Utilization Other**

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

2.	Other Type of Practitioner Specify:	[24 Hr Covid Drive Thru Testing]
----	--	----------------------------------

**Health Care Utilization**

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

**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:** 10831060

**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	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** RESPIRATORY TREATMENT

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Respiratory Treatment**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Covid-19]  Date of Diagnosis: Dec/2/2020
3.	Toxicity Grade:	1

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**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:** 10831060

**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 Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Illness Details**

1.	Category of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
2.	Subcategory of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
3.	Was a diagnosis obtained?	Not Applicable _____	<a href="#">Comments</a>
4.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>

**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:** 10831060

**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 Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Lab Chemistry Details**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5.b	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.c	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5.d	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.e	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5 f	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.g	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Laboratory Data Hematology**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5.b	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.c	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5.d	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.e	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5 f	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.g	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5 h	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.i	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5.j	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f94\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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.	Dec/4/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	142	86	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** VITAL SIGNS - COVID

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Vital Signs**

1.	Date:	Dec/4/2020
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[142]
	Diastolic:	[86]
	Respiratory Rate in respirations/minute:	[14]
	Heart Rate in beats/minute:	[69]

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
----	-------	-------------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO <sub>2</sub>	FiO <sub>2</sub> (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Oxygenation Parameters**

1.	Date Time of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**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:** 10831060

**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	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Concomitant Medications**

1.	What is the medication identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
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 _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

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**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:** 10831060

**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	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** IMAGING

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Imaging**

1.	Date of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Location of Assessment:	Not Applicable _____	<a href="#">Comments</a>
3.	Type of Imaging Exam:	Not Applicable _____	<a href="#">Comments</a>
4.	Assessment:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Date of Visit**

1.	Date of Visit	Dec/11/2020
2.	Erroneous Visit	ERRONEOUS VISIT

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_B
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Date of First Symptom Started:	Not Applicable _____ //	<a href="#">Comments</a>
3.	Symptoms Ongoing?	Not Applicable _____	<a href="#">Comments</a>

**Symptoms**

4.a	Symptoms:	FEVER	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.b	Symptoms:	NEW OR INCREASED COUGH	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.d	Symptoms:	CHILLS	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

4 f	Symptoms:	NEW LOSS OF TASTE OR SMELL	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.g	Symptoms:	NEW OR INCREASED SORE THROAT	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4 h	Symptoms:	DIARRHEA	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
4.i	Symptoms:	VOMITING	
	Was symptom present?	Not Applicable _____	<a href="#">Comments</a>
<b>Symptoms - Other</b>			
5.	Symptoms - Other Text:	Not Applicable _____ [ ]	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Microbiology Specimen**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**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	Not Applicable _____	<a href="#">Comments</a>
2.	Sample Type	Not Applicable _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Applicable _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ [ ]
----	-----------	--------------------------------

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**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	Not Applicable _____	<a href="#">Comments</a>
2.	Sample Type	Not Applicable _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Applicable _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	Not Applicable _____ [ ]
-----	-----------	--------------------------------

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Form Comments](#)[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST	
	Occurrence of Visits or Contacts:	Not Applicable	<a href="#">Comments</a>
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM	
	Occurrence of Visits or Contacts:	Not Applicable	<a href="#">Comments</a>
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN	
	Occurrence of Visits or Contacts:	Not Applicable	<a href="#">Comments</a>
1.d	Physician or Healthcare Professional:	URGENT CARE	
	Occurrence of Visits or Contacts:	Not Applicable	<a href="#">Comments</a>
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION	
	Occurrence of Visits or Contacts:	Not Applicable	<a href="#">Comments</a>
1.f	Physician or Healthcare Professional:	OTHER	
	Occurrence of Visits or Contacts:	Not Applicable	<a href="#">Comments</a>

**Health Care Utilization Other**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** HEALTH CARE UTILIZATION

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

2.	Other Type of Practitioner Specify:	Not Applicable _____ [ ]	<a href="#">Comments</a>
<b>Health Care Utilization</b>			
3.	Has the subject been hospitalized due to potential COVID-19 illness?	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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	<a href="#">Repeating Pages</a>

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** RESPIRATORY TREATMENT

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Respiratory Treatment**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Illness Details**

1.	Category of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	Not Applicable _____	<a href="#">Comments</a>
3.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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 Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Illness Details**

1.	Category of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
2.	Subcategory of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
3.	Was a diagnosis obtained?	Not Applicable _____	<a href="#">Comments</a>
4.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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 Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

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

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**Lab Chemistry Details**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5.b	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.c	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5.d	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.e	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5 f	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.g	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Laboratory Data Hematology**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5.b	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.c	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5.d	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.e	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5 f	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.g	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5 h	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.i	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

5.j	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - COVID

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	Not Applicable	Not Applicable	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled

**Form:** VITAL SIGNS - COVID

Visit on Dec/11/2020

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
----	-------	-------------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	1	
	Systolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Diastolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Respiratory Rate in respirations/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Heart Rate in beats/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
----	-------	-------------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO <sub>2</sub>	FiO <sub>2</sub> (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Oxygenation Parameters**

1.	Date Time of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Concomitant Medications**

1.	What is the medication identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
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 _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** IMAGING

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** IMAGING

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Imaging**

1.	Date of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Location of Assessment:	Not Applicable _____	<a href="#">Comments</a>
3.	Type of Imaging Exam:	Not Applicable _____	<a href="#">Comments</a>
4.	Assessment:	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/05/2021

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Date of Visit**

1.	Date of Visit	Jan/5/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/05/2021

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/5/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRCJ9L]
5.b	Sample ID	[BM3M47]
5.c	Sample ID	[BM3M48]

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**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Aug/07/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Date of Visit**

1.	Date of Visit	Aug/7/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Aug/07/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Aug/07/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/7/2020  Contact Outcome: VISIT ARRANGED, BUT NOT ATTENDED
3.	Comments:	[Site has been in contact with this subject. Uns visits were offered and subject declined]

**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on  
Aug/08/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Date of Visit**

1.	Date of Visit	Aug/8/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on Aug/08/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------



**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on Aug/08/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/8/2020  Contact Outcome: VISIT ARRANGED, BUT NOT ATTENDED
3.	Comments:	[Site has been in contact with this subject. Uns visits were offered and subject declined]

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**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Aug/11/2020

**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:** 10831060

**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/11/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Aug/11/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
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**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Aug/11/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/11/2020  Contact Outcome: VISIT ARRANGED, BUT NOT ATTENDED
3.	Comments:	[Site has been in contact with this subject. Uns visits were offered and subject declined]

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 4 - Unscheduled Visit on  
Aug/12/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Unplanned 4 - Unscheduled Visit on  
Aug/12/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

**Header Text:** c4591001

**Visit:** Unplanned 4 - Unscheduled Visit on Aug/12/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/12/2020  Contact Outcome: VISIT ARRANGED, BUT NOT ATTENDED
3.	Comments:	[Site has been in contact with this subject. Uns visits were offered and subject declined]

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 5 - Unscheduled Visit on  
Aug/13/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Date of Visit**

1.	Date of Visit	Aug/13/2020
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Unplanned 5 - Unscheduled Visit on  
Aug/13/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

**Header Text:** c4591001

**Visit:** Unplanned 5 - Unscheduled Visit on  
Aug/13/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/13/2020  Contact Outcome: VISIT ARRANGED, BUT NOT ATTENDED
3.	Comments:	[Site has been in contact with this subject. Uns visits were offered and subject declined]

**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on  
Aug/14/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Date of Visit**

1.	Date of Visit	Aug/14/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on  
Aug/14/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
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**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on  
Aug/14/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/14/2020  Contact Outcome: VISIT NOT ARRANGED, UNABLE TO ATTEND
3.	Comments:	[ ]

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on  
Aug/15/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Date of Visit**

1.	Date of Visit	Aug/15/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on Aug/15/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Unplanned Assessments**

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on  
Aug/15/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/15/2020  Contact Outcome: VISIT NOT ARRANGED, UNABLE TO ATTEND
3.	Comments:	[Site has been in contact with this subject. Uns visits were offered and subject declined]

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**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Aug/14/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**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 1 -  
Unscheduled Visit on Dec/11/2020

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**Date of Visit**

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

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	COVID_BR1
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**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB 1 -  
Unscheduled Visit on Dec/11/2020

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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: Dec/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRCJ7H]
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

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: 10831060

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.	ADVERSE EVENT	1	Worsening of Abdominal Pain	Aug/14/2020 00:00	NO End Date Time: Aug/24/2020 11:32	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Post Operative Ileus	Aug/18/2020 00:00	NO End Date Time: Aug/23/2020 00:00	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Ruptured diverticulum	Aug/14/2020 00:00	NO End Date Time: Aug/24/2020 00:00	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Phlegmon Formation	Aug/20/2020 00:00	NO End Date Time: Aug/20/2020 00:00	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	Diverticulitis	Aug/20/2020 00:00	NO End Date Time: Aug/25/2020 UNK:UNK	<a href="#">Repeating Pages</a>
6.	ADVERSE EVENT	6	Small Bowel Obstruction	Aug/20/2020 00:00	NO End Date Time: Aug/20/2020 00:00	<a href="#">Repeating Pages</a>
7.	ADVERSE EVENT	7	Diverticulitis	Aug/26/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>
8.	ADVERSE EVENT	8	Fatigue	Mar/7/2021 00:00	NO End Date Time:	<a href="#">Repeating Pages</a>

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

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: 10831060

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
					Mar/8/2021 00:00	
9.	ADVERSE EVENT	9	Slight Headache	Mar/7/2021 00:00	NO End Date Time: Mar/8/2021 00:00	<a href="#">Repeating Pages</a>
10.	ADVERSE EVENT	10	Injection Site Pain-Left	Mar/7/2021 00:00	NO End Date Time: Mar/8/2021 00:00	<a href="#">Repeating Pages</a>
11.	ADVERSE EVENT	11	Muscle Aches	Mar/7/2021 00:00	NO End Date Time: Mar/8/2021 00:00	<a href="#">Repeating Pages</a>

090177e196ae3f94\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:** 10831060

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of Abdominal Pain]
4.	Start Date Time:	Aug/14/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/24/2020 11:32
6.	Toxicity Grade:	4
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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: [Ruptured Diverticulum]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
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	[ ]

090177e196ae3f94\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:** 10831060

**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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Post Operative Ileus]
4.	Start Date Time:	Aug/18/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/23/2020 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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**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

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: [Surgical Side Effect]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
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	[ ]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Ruptured diverticulum]
4.	Start Date Time:	Aug/14/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/24/2020 00:00
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? YES  Is this serious event life threatening? YES  Other medically important serious event NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**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

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: [Infection]
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[2020319554]

090177e196ae3f94\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:** 10831060

**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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Phlegmon Formation]
4.	Start Date Time:	Aug/20/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/20/2020 00:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**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

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

090177e196ae3f94\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:** 10831060

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Diverticulitis]
4.	Start Date Time:	Aug/20/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/25/2020 UNK:UNK
6.	Toxicity Grade:	4
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Small Bowel Obstruction]
4.	Start Date Time:	Aug/20/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/20/2020 00:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1083) Benchmark Research

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

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**Header Text:** c4591001

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**Form Status:** Data Complete

**Site Name:** (1083) Benchmark Research

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Diverticulitis]
4.	Start Date Time:	Aug/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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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: [Medical event]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1083**Subject No:** 10831060**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, 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)	[Fatigue]
4.	Start Date Time:	Mar/7/2021 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/8/2021 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:	RELATED

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

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**Form Status:** Data Complete, Frozen

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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?:	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:** 10831060**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, 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:	[9]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Slight Headache]
4.	Start Date Time:	Mar/7/2021 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/8/2021 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:	RELATED

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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?:	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	[ ]



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1.	Category:	ADVERSE EVENT
2.	AE ID:	[10]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection Site Pain-Left]
4.	Start Date Time:	Mar/7/2021 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/8/2021 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:	RELATED

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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?:	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:** 10831060**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, 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:	[11]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Muscle Aches]
4.	Start Date Time:	Mar/7/2021 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Mar/8/2021 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:	RELATED

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1083) Benchmark Research

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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**Medication Error**

1.	Category:	Not Applicable _____	<a href="#">Comments</a>
2.	Medication Error (Type of Medication Error):	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Is the medication error still ongoing?	Not Applicable _____	<a href="#">Comments</a>
5.	Latest Action Taken with Study Treatment:	Not Applicable _____	<a href="#">Comments</a>
6.	Was a Concomitant Medication given?	Not Applicable _____	<a href="#">Comments</a>
7.	Was a Non-Drug Treatment given?	Not Applicable _____	<a href="#">Comments</a>
8.	Did the Medication Error cause the subject to be discontinued from the study?	Not Applicable _____	<a href="#">Comments</a>
9.	Was this medication error associated with any adverse events?	Not Applicable _____	<a href="#">Comments</a>
10.	Serious Adverse Event Number: For Pfizer Use Only	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**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:** 10831060

**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.	1	VACCINATION S	NO	Influenza Vaccine	Feb/2/2021	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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**Concomitant Medications**

1.	What is the medication identifier?	[1]	<a href="#">Comments</a>
2.	Category:	VACCINATIONS	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	NO	<a href="#">Comments</a>
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).	[Influenza Vaccine]	<a href="#">Comments</a>
5.	Date:	Feb/2/2021	<a href="#">Comments</a>

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**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:** 10831060

**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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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**Concomitant Medications**

1.	What is the medication identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____ [ ]	<a href="#">Comments</a>
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 _____ [ ]	<a href="#">Comments</a>
5.	Dose:	Not Applicable _____ [ ]	<a href="#">Comments</a>
6.	Dose Unit:	Not Applicable _____ [ ]	<a href="#">Comments</a>
7.	Dose Frequency:	Not Applicable _____ [ ]	<a href="#">Comments</a>
8.	Route:	Not Applicable _____ [ ]	<a href="#">Comments</a>
9.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
10.	Ongoing?	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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**Radiation Treatment**

1.	Category:	Not Applicable _____	<a href="#">Comments</a>
2.	What is the treatment Identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
4.	Treatment:	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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1.	Transfusion Type:	Not Applicable _____	<a href="#">Comments</a>
2.	Date of Transfusion:	Not Applicable _____ //	<a href="#">Comments</a>

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**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:** 10831060    **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:** 10831060    **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:** VACCINATION

**Form Version:** 10-Dec-2020 02:26    **Form Status:** Not Started

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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?	

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**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:** 10831060    **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:** 10831060    **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:** 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:** 10831060

**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/13/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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:** TREATMENT UNBLINDED

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/14/2021
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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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:** 10831060

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**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](#)

**Date of Visit**

1.	Date of Visit	Mar/6/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**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](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/6/2021
----	--------------	---

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**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:** V101\_VAX3

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Mar/6/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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: Mar/6/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BM2L3V]
5.b	Sample ID	[BKN1XT]
<del>5.c</del>	Sample ID	<del>[BKN1YC]</del>
5.d	Sample ID	[BM2L4C]

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

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

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/6/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BKN1YC]
-----	-----------	----------

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** VACCINATION

**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](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/6/2021 11:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1083

**Subject No:** 10831060

**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:** V102\_VAX4

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

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

**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	[ ]
----	-----------	-----

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Not Started

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

**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?	

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1083

**Subject No:** 10831060

**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:** V103\_MONTH1

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1083

**Subject No:** 10831060

**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:** V104\_MONTH6

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1083

**Subject No:** 10831060

**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:** V105\_MONTH18

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

**Contact Outcome**

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



**Header Text:** c4591001

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

**Form:** DISPOSITION - TREATMENT

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

**Form Status:** Not Started

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**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	DISCONTINUED
2.	Subject Status Date	Aug/14/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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
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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**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

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Item	Date	User	Comment
Form	Aug-07-2020 14:03:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Aug-07-2020 14:02:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Aug-06-2020 18:12:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Aug-06-2020 17:58:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Aug-06-2020 17:57:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Aug-06-2020 17:56:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Aug-06-2020 17:55:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f94\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:** 10831060

**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

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Item	Date	User	Comment
1.h	Aug-19-2020 18:06:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Site added a late entry to medical history as subject did not disclose this information during medical history review

**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**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

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Item	Date	User	Comment
1.h	Aug-19-2020 18:06:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Site added a late entry to medical history as subject did not disclose this information during medical history review

**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**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.h	Aug-19-2020 18:06:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Site added a late entry to medical history as subject did not disclose this information during medical history review



**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**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.h	Aug-19-2020 18:06:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Site added a late entry to medical history as subject did not disclose this information during medical history review

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Oct-23-2020 15:08:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	15SEP2020 PI decision to not do V2 due to SAE and unstable medical conditions. Subject did not discontinue and will be followed up for safety and data collection <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - 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	Oct-23-2020 15:08:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	15SEP2020 PI decision to not do V2 due to SAE and unstable medical conditions. Subject did not discontinue and will be followed up for safety and data collection
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - 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	Oct-23-2020 15:08:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	15SEP2020 PI decision to not do V2 due to SAE and unstable medical conditions. Subject did not discontinue and will be followed up for safety and data collection
			Not Applicable

**Header Text:** c4591001

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	PI decision due to SAE and unstable medical conditions subject did not get V2 eDiary not applicable
			Not Applicable

**Header Text:** c4591001

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
1	Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	PI decision due to SAE and unstable medical conditions subject did not get V2 eDiary not applicable
			Not Applicable

**Header Text:** c4591001

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	PI decision due to SAE and unstable medical conditions subject did not get V2 eDiary not applicable
			Not Applicable

**Header Text:** c4591001

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
2.b	Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	PI decision due to SAE and unstable medical conditions subject did not get V2 eDiary not applicable
			Not Applicable



**Header Text:** c4591001

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Item	Date	User	Comment
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**Header Text:** c4591001

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Item	Date	User	Comment
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**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

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Item	Date	User	Comment
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**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

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**Generated By:** (b) (4)

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Item	Date	User	Comment
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Item	Date	User	Comment
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**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

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**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

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Item	Date	User	Comment
Form	Dec-04-2020 16:57:55 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

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Visit on Dec/04/2020

**Form:** RESPIRATORY TREATMENT - Comments

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**Subject No:** 10831060

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**Generated By:** (b) (4)

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Item	Date	User	Comment
1	Dec-04-2020 16:57:55 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Visit on Dec/04/2020

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

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Item	Date	User	Comment
2	Dec-04-2020 16:57:55 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
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**Header Text:** c4591001

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Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
Form	Dec-04-2020 17:14:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

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Item	Date	User	Comment
1	Dec-04-2020 17:14:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
2	Dec-04-2020 17:14:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
Form	Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

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**Generated By:** (b) (4)

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**Form Version:** 06-Jul-2020 21:52

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

**Site No:** 1083

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**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
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**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Dec-04-2020 16:58:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
1	Dec-04-2020 16:58:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
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**Form Version:** 06-Jul-2020 21:55

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

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**Generated By:** (b) (4)

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

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Item	Date	User	Comment
2	Dec-04-2020 16:58:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
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**Site No:** 1083

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**Generated By:** (b) (4)

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

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Item	Date	User	Comment
3	Dec-04-2020 16:58:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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Item	Date	User	Comment
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Item	Date	User	Comment
6	Dec-04-2020 16:58:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
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**Header Text:** c4591001

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Visit on Dec/04/2020

**Form:** IMAGING - Comments

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

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Item	Date	User	Comment
1	Dec-04-2020 16:58:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Generated By:** (b) (4)

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

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Item	Date	User	Comment
2	Dec-04-2020 16:58:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** IMAGING - Comments

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

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**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
3	Dec-04-2020 16:58:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
4	Dec-04-2020 16:58:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1083

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**Subject No:** 10831060

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

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Item	Date	User	Comment
1	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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**Form Version:** 10-Dec-2020 02:29

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

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

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Item	Date	User	Comment
2	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
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**Visit:** POT\_COVID\_ILL 2

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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**Form Version:** 10-Dec-2020 02:29

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**Site No:** 1083

**Site Name:** (1083) Benchmark Research

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**Generated By:** (b) (4)

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Item	Date	User	Comment
3	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

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**Generated By:** (b) (4)

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

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Item	Date	User	Comment
4.a	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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**Site No:** 1083

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**Generated By:** (b) (4)

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

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Item	Date	User	Comment
4.b	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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**Form Version:** 10-Dec-2020 02:29

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**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
4.c	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
4.d	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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**Form Version:** 10-Dec-2020 02:29

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
4.e	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
4.f	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
Comments

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
4.g	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
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**Header Text:** c4591001

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
4.h	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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**Form Version:** 10-Dec-2020 02:29

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

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**Generated By:** (b) (4)

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Item	Date	User	Comment
4.i	Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

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

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Item	Date	User	Comment
1	Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Form:** MICROBIOLOGY SPECIMEN - Comments

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
5	Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
6	Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

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**Site No:** 1083

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**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
7	Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
8	Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
9	Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Dec-15-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous <hr/> Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

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

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

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**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
1	Dec-15-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
2	Dec-15-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
3	Dec-15-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
4	Dec-15-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Dec-15-2020 11:29:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous <hr/> Not Applicable
Form	Dec-14-2020 17:14:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Visit marked as erroneous as the symptoms from COVID Illness A/#1 were not resolved and visit B should not have been conducted. Newly reported symptom has been added to COV ILL A/#1

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
1	Dec-15-2020 11:29:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
2	Dec-15-2020 11:29:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
3	Dec-15-2020 11:29:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous <hr/> Not Applicable
3	Dec-14-2020 17:14:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Visit marked as erroneous as the symptoms from COVID Illness A/#1 were not resolved and visit B should not have been conducted. Newly reported symptom has been added to COV ILL A/#1



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
4	Dec-15-2020 11:29:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** HEALTH CARE UTILIZATION - Comments

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
1.a	Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
1.b	Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
1.c	Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
1.d	Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
1.e	Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
1.f	Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
1	Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
2	Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

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**Generated By:** (b) (4)

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

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Item	Date	User	Comment
3	Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
4	Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
5	Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
6	Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Dec-15-2020 11:52:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1083

**Subject No:** 10831060

**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

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Item	Date	User	Comment
1	Dec-15-2020 11:52:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1083

**Subject No:** 10831060

**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

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Item	Date	User	Comment
2	Dec-15-2020 11:52:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1083

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**Site Name:** (1083) Benchmark Research

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

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Item	Date	User	Comment
3	Dec-15-2020 11:52:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Dec-11-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
1	Dec-11-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

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**Generated By:** (b) (4)

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Item	Date	User	Comment
2	Dec-11-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

**Form Version:** 17-Jul-2020 21:55

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Item	Date	User	Comment
3	Dec-11-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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

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**Generated By:** (b) (4)

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

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Item	Date	User	Comment
4	Dec-11-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
1	Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

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**Generated By:** (b) (4)

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

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Item	Date	User	Comment
2	Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
5.j	Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
Comments

**Form Version:** 30-Jul-2020 21:28

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

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**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

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**Generated By:** (b) (4)

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

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Item	Date	User	Comment
5.j	Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 30-Jul-2020 21:27

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

**Site No:** 1083

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**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Dec-15-2020 11:50:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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Visit on Dec/11/2020

**Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 30-Jul-2020 21:27

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

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Item	Date	User	Comment
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**Header Text:** c4591001

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Visit on Dec/11/2020

**Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 30-Jul-2020 21:27

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Item	Date	User	Comment
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**Header Text:** c4591001

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**Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 30-Jul-2020 21:27

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Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments

**Form Version:** 30-Jul-2020 21:28

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**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

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**Header Text:** c4591001

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**Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments

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Item	Date	User	Comment
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**Header Text:** c4591001

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**Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments

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Item	Date	User	Comment
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**Header Text:** c4591001

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Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
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**Header Text:** c4591001

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Visit on Dec/11/2020

**Form:** OXYGENATION PARAMETERS - Comments

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Item	Date	User	Comment
1	Dec-11-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
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**Header Text:** c4591001

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Item	Date	User	Comment
3	Dec-11-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
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Item	Date	User	Comment
Form	Dec-11-2020 13:50:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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1	Dec-11-2020 13:50:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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**Header Text:** c4591001

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

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Form	Jan-26-2021 16:56:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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**Header Text:** c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - Comments

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

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**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
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Form	Jan-26-2021 16:56:32 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
1	Mar-09-2021 13:58:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Jan-26-2021 16:56:32 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1083

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**Generated By:** (b) (4)

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Item	Date	User	Comment
2	Mar-09-2021 13:58:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Jan-26-2021 16:56:32 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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3	Jan-26-2021 16:56:32 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

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

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4	Jan-26-2021 16:56:32 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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

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Item	Date	User	Comment
Form	Jan-26-2021 17:11:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

**Site No:** 1083

**Subject No:** 10831060

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Comments

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

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**Subject No:** 10831060

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

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Item	Date	User	Comment
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**Subject No:** 10831060

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**Form:** CONCOMITANT MEDICATIONS - PROHIBITED -  
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**Form Status:** Data Complete, Frozen, Verified

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Item	Date	User	Comment
9	Jan-26-2021 17:11:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Comments

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
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**Header Text:** c4591001

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Jan-26-2021 17:12:32 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Jan-26-2021 17:12:32 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Site No:** 1083

**Subject No:** 10831060

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
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**Header Text:** c4591001

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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Item	Date	User	Comment
3	Jan-26-2021 17:12:32 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
5	Jan-26-2021 17:12:32 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
6	Jan-26-2021 17:12:32 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Jan-26-2021 17:12:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Form:** TRANSFUSIONS - Comments

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

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Jan-26-2021 17:12:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Form:** TRANSFUSIONS - Comments

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**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Jan-26-2021 17:12:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

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**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Item	Date	User	Comment
Form	Mar-08-2021 17:47:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Laurence Chu	Approved	Mar-11-2021 15:57:00 (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	Jan-26-2021 16:44:46 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Laurence Chu	Approved	Jan-20-2021 16:33:21 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3f94\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, Verified

**Site No:** 1083

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(b) (6)	N/A	Dec-04-2020 14:24:47 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Laurence Chu	Approved	Nov-16-2020 17:07:06 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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(b) (6)	N/A	Nov-13-2020 12:49:51 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Laurence Chu	Approved	Oct-23-2020 16:16:04 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

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(b) (6)	N/A	Oct-22-2020 15:06:11 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Laurence Chu	Approved	Oct-12-2020 12:45:51 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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(b) (6)	N/A	Oct-08-2020 14:34:06 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Laurence Chu	Approved	Oct-01-2020 17:50:12 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Form Version:** 22-Apr-2020 21:04

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**Site Name:** (1083) Benchmark Research

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**Subject Initials:** ---

**Generated By:** (b) (4)

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

(b) (6)	N/A	Sep-24-2020 15:22:47 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Laurence Chu	Approved	Sep-24-2020 11:27:20 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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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 14:47:42 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Laurence Chu	Approved	Sep-22-2020 13:33:41 (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, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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.

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-06-2020 17:52:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-06-2020 17:52:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-06-2020 17:52:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/6/2020	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**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:** 10831060**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-18-2020 03:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	UNPLANNED visit added
Aug-14-2020 11:03:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Per Site Coordinator an UNPL phone contact was made on same day eDiary alerted site. An UNPL visit offered by the site and was declined by the subject. Site is making daily follow up calls to the subject to get his current status
Aug-13-2020 07:45:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	PDQ: Subject has reported Temperature as 102.1 F in eDiary data on 11Aug2020. Please confirm if an UNPL contact was made and update the data as appropriate.
Aug-06-2020 17:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10831060	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
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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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

Aug-24-2020 03:29:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Date of Birth updated to (b) (6) -1975 in SDB. Issue resolved
Aug-20-2020 14:42:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Follow up report was faxed on 19-AUG-2020 with the information requested
Aug-19-2020 08:52:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE Recon: AER #2020319554, Date of Birth is reported as (b) (6) -1975" however, in the Study Database Date of Birth is blank. Please confirm Date of Birth. If safety database is required, also submit a follow-up SAE Report form per reporting procedures.
Aug-06-2020 17:52:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1975	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-24-2020 03:29:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Gender updated to Male in SDB. Issue resolved
Aug-20-2020 14:41:59 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Follow up report was faxed on 19-AUG-2020 with

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**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:** 10831060 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:11

Time (US & Canada)				the information requested
Aug-19-2020 08:51:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE Recon: AER #2020319554, Gender is reported as "Male" however, in the Study Database Gender is "NO DATA". Please confirm Gender. If safety database is required, also submit a follow-up SAE Report form per reporting procedures.
Aug-06-2020 17:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-06-2020 17:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-06-2020 17:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3f94\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:** 10831060

**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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-17-2020 03:49:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Sep-15-2020 15:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject will not be getting Vaccination 2 per PI. Waiting for subjects SAE condition to stabilize and will be brought back for safety follow up
Sep-15-2020 12:46:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Need to track/review for Vaccination 2
Sep-08-2020 23:26:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidat e	Need to track/review for Vaccination 2
Sep-08-2020 16:02:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	To be determined by PI
Sep-07-2020 05:16:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM 2: Thanks for your response. Please provide planned vaccination date V2.
Sep-04-2020 15:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per Sponsor- Site is not to have an open or unanswered queries left at end

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:02

Site No: 1083

Subject No: 10831060

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

				of business day
Sep-04-2020 09:15:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM1: Thank you for the response. Please keep this query open at your end. Once visit is performed, kindly update vaccination details and rest of the visit pages and then respond to the query.
Sep-03-2020 12:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject has not returned for V2 secondary to SAE.
Sep-03-2020 06:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Details on visit 'V2VX2L' are missing. Kindly consider to update or else clarify. Thank you.
Aug-20-2020 05:51:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-18-2020 12:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Site has been in contact with this subject. Uns visits were offered and subject declined
Aug-18-2020 06:27:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	per section 8.41 of ecrf completion requirements, if a subject has a severe reaction they must be contacted. As such, this contact must be documented in the

090177e196ae3f94\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:** 10831060**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

				UNPL log and a comment added to state why a UNPL visit will not occur. please update. thanks
Aug-17-2020 12:26:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Site has been in contact with this subject. Uns visits were offered and subject declined.
Aug-17-2020 04:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	has subject been contacted? if not, please clarify. if they have, please update the UNPL log as appropriate. thanks
Aug-14-2020 11:03:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Aug-13-2020 21:17:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Subject reported fever greater than 102.1F in the e-diary on 11 Aug however, no unplanned visit has occurred. Please can you confirm if subject has been contacted? Update UNPL as appropriate
Aug-06-2020 17:55:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/6/2020	Initial Entry

**2. Erroneous Visit**

**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**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

Date	Location	User	Value	Reason
Aug-20-2020 14:17:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	FU#1 received by DSU and AE log updated.
Aug-18-2020 12:00:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Drug Safety Unit received an initial SAE Form for increased abdominal pain. Please follow-up and respond to DSU queries. Add SAE in EDC.

**Header Text:** c4591001

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

**Form:** DISPOSITION - SCREENING - 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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

Date	Location	User	Value	Reason
Aug-07-2020 17:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/6/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-07-2020 17:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-07-2020 17:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f94\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: 10831060

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

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I.a

Date	Location	User	Value	Reason
Aug-25-2020 15:17:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Allergic Rhinitis-Seasonal <b>Start Date:</b> UNK/UNK/1976 <b>Ongoing:</b> YES	Transcription Error
Aug-07-2020 17:57:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Allergic Rhinitis <b>Start Date:</b> UNK/UNK/1976 <b>Ongoing:</b> YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 17:57:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 20:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-25-2020 15:17:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae3f94\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: 10831060

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-25-2020 15:17:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Allergic Rhinitis-Seasonal	Transcription Error
Aug-24-2020 21:12:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery:the query should be unfrozen for them to enter information. thanks
Aug-21-2020 12:53:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please thaw eCRF so site may updated to -Seasonal Allergic Rhinitis
Aug-21-2020 03:29:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Allergic Rhinitis : Please can you update to indicate the allergen? Thanks
Aug-21-2020 01:56:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	ClinQuery: Allergic Rhinitis : Please can you update to indicate the allergen? Thanks
Aug-07-2020 17:57:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Allergic Rhinitis	Initial Entry

***1.a Start Date:***

Date	Location	User	Value	Reason
Aug-07-2020 17:57:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1976	Initial Entry

***1.a Ongoing:***

090177e196ae3f94\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:** 10831060

**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

Date	Location	User	Value	Reason
Aug-07-2020 17:57:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*1.b*

Date	Location	User	Value	Reason
Aug-07-2020 17:58:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Numbe 2</b> <b>r:</b> <b>Medical History</b> Umbilical h <b>Term:</b> ernia <b>Start Date:</b> UNK/UNK/ 2010 <b>Ongoing:</b> YES	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1083**Subject No:** 10831060**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-07-2020 17:58:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 17:58:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Umbilical hernia	Initial Entry

***1.b Start Date:***

Date	Location	User	Value	Reason
Aug-07-2020 17:58:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Aug-07-2020 17:58:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Aug-07-2020 17:59:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 3 <b>Number:</b> <b>Medical H</b> Partial Achilles Ten <b>istory Ter</b> don Tear-Right Foo <b>m:</b> t <b>Start Date</b> Mar/UNK/2018 :	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831060

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

			<b>Ongoing:</b> NO End Date:  Mar/UNK/2018	
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**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 17:59:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 17:59:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Partial Achilles Tendon Tear- Right Foot	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 17:59:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/UNK/2018	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 17:59:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Mar/UNK/2018	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-07-2020 18:00:37 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numbe 4	Initial Entry

090177e196ae3f94\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: 10831060

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

Time (US & Canada)			r: Medical History Hair Loss Term: Start Date: UNK/UNK/ 2000 Ongoing: YES	
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**I.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 18:00:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:00:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Hair Loss	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 18:00:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2000	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 18:00:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Aug-07-2020 18:01:59	ACV0PFEINFP6000	auto calc	<u>Data Entry:</u>	Initial Entry

090177e196ae3f94\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:** 10831060**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(UTC-06:00) Central  
Time (US & Canada)

(autocalc)

**Line/MH Nu** 5**mber:****Medical History Term:** Pectoralis Tendon Tear-Right**Start Date:** UNK/UNK/2013**Ongoing:** NO

End Date:

UNK/UNK/2013

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

Date	Location	User	Value	Reason
Aug-07-2020 18:01:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:01:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pectoralis Tendon Tear-Right	Initial Entry

***I.e Start Date:***

Date	Location	User	Value	Reason
Aug-07-2020 18:01:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

***I.e Ongoing:***

Date	Location	User	Value	Reason
Aug-07-2020 18:01:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2013	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**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.f*

Date	Location	User	Value	Reason
Aug-07-2020 18:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 6</b> <b>umber:</b> <b>Medical Hi</b> Right Foot Achille <b>story Term</b> s Tendon Repair : <b>Start Date:</b> Mar/UNK/2018 <b>Ongoing:</b> NO End Date: Mar/UNK/201 8	Initial Entry

090177e196ae3f94\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:** 10831060**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.f Line/MH Number:***

Date	Location	User	Value	Reason
Aug-07-2020 18:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Right Foot Achilles Tendon Repair	Initial Entry

***1.f Start Date:***

Date	Location	User	Value	Reason
Aug-07-2020 18:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/UNK/2018	Initial Entry

***1.f Ongoing:***

Date	Location	User	Value	Reason
Aug-07-2020 18:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Mar/UNK/2018	Initial Entry

***1.g***

Date	Location	User	Value	Reason
Aug-07-2020 18:04:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 7</b> <b>umber:</b> <b>Medical Hi</b> Pectoralis tendon <b>story Term</b> Tear Repair-Right : <b>Start Date:</b> UNK/UNK/2013	Initial Entry



**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1083  
**Subject No:** 10831060  
**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

			<b>Ongoing:</b> NO End Date:  UNK/UNK/2013	
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**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 18:04:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:04:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pectoralis tendon Tear Repair -Right	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 18:04:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 18:04:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2013	Initial Entry

**I.h**

Date	Location	User	Value	Reason
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090177e196ae3f94\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:** 10831060

**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-19-2020 18:05:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8 <b>Medical History:</b> Stomach Cr <b>Term:</b> amps <b>Start Date:</b> Aug/3/2020 <b>Ongoing:</b> YES	Initial Entry
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1083

Subject No: 10831060

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.h Line/MH Number:**

Date	Location	User	Value	Reason
Aug-19-2020 18:05:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 19:23:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-02-2020 13:13:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No, Late entry to medical history due to subject not reporting during screening visit. Symptoms occurred prior to screening and randomization
Sep-01-2020 21:21:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery: does this subject meet IC3 as a result of this medhx start date? thanks
Aug-31-2020 17:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Late entry to medical history due to subject not reporting during screening visit
Aug-27-2020 17:34:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Stomach Cramps: Please can you confirm subject meets IC3 as a start date of this medhx?

090177e196ae3f94\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:** 10831060

**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

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

Date	Location	User	Value	Reason
Aug-19-2020 18:05:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Stomach Cramps	Initial Entry

***1.h Start Date:***

Date	Location	User	Value	Reason
Aug-19-2020 18:05:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/3/2020	Initial Entry

***1.h Ongoing:***

Date	Location	User	Value	Reason
Aug-19-2020 18:05:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f94\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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Date:**

Date	Location	User	Value	Reason
Aug-07-2020 18:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/6/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-07-2020 18:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 180.2	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-07-2020 18:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-07-2020 18:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 68.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-07-2020 18:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

Aug-07-2020 18:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 27.4	Initial Entry
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7.a

Date	Location	User	Value	Reason
Aug-07-2020 18:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier: Temperature: 98.5 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-07-2020 18:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-07-2020 18:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-07-2020 18:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3f94\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:** 10831060

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE - 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-07-2020 18:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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**Header Text:** c4591001

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

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

**Site No:** 1083

**Subject No:** 10831060

**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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-07-2020 18:05:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/6/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-07-2020 18:05:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 43386	Initial Entry

090177e196ae3f94\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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-07-2020 18:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-07-2020 18:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-01-2020 04:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed by DM: (b) (6)
Aug-31-2020 17:23:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Aug-28-2020 13:44:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Barcode BP6V4H is missing in inform. Please review and update accordingly or clarify.
Aug-11-2020 12:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-10-2020 07:44:45 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes,

090177e196ae3f94\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:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

Time (US & Canada)				however no barcodes are entered. Please review and correct as appropriate.
Aug-07-2020 18:05:42 (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-07-2020 18:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/6/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-11-2020 12:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP6V56	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-11-2020 12:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP6V56	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Aug-11-2020 12:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP6V57	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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 12:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP6V57	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-11-2020 12:21:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP6V58	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 12:21:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP6V58	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-11-2020 12:22:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BG1VL5	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 12:22:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BG1VL5	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae3f94\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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

Aug-11-2020 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BG1VL6	Initial Entry
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 12:22:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BG1VL6	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-21-2020 16:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error <b>(DELETED)</b>
Aug-21-2020 16:05:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error
Aug-21-2020 15:57:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP6V4F	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 16:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error <b>(DELETED)</b>
Aug-21-2020 16:05:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Aug-21-2020 15:57:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP6V4F	Initial Entry

090177e196ae3f94\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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.g**

Date	Location	User	Value	Reason
Aug-21-2020 15:59:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP6V4H</b>	Transcription Error <b>(DELETED)</b>
Aug-21-2020 15:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP6V4H</b>	Initial Entry

**5.g Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 15:59:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP6V4H	Transcription Error <b>(DELETED)</b>
Aug-21-2020 15:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP6V4H	Initial Entry

090177e196ae3f94\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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-07-2020 18:06:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-07-2020 18:06:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-12-2020 10:50:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 3: Closed	Response satisfies query
Sep-11-2020 17:00:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	2 Nasal swab BARCODES for 1060 were put on separate sample control forms during a shipment change. We show BP6V4F to be the correct one but lab has BP6V4H and is being held. Site scanned second barcode for query resolution. Either one is 1060 not diff sub

090177e196ae3f94\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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Sep-11-2020 16:52:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Sep-03-2020 15:45:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Sep-02-2020 13:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	BP6V4F Original data is correct. Per Sample Control Form Source, BP6V4F was shipped 8/6/2020 Per Inform Audit Trail BP6V4H was entered in error and was deleted
Sep-01-2020 18:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Barcode BP6V4H was received by the lab. Please confirm and update accordingly
Aug-11-2020 12:20:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-10-2020 07:46:27 (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-07-2020 18:06:14	ACV0PFEINFP6000	auto query	Query 1: Candidate	'Sample

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**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:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

(UTC-06:00) Central Time (US & Canada)		(autoquery)		Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-07-2020 18:06:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/6/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-14-2020 13:02:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP6V4F</b>	Transcription Error <b>(DELETED)</b>
Aug-11-2020 12:25:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP6V4F</b>	Transcription Error
Aug-11-2020 12:20:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP6V56</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-14-2020 13:02:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>BP6V4F</b>	Transcription Error <b>(DELETED)</b>
Sep-12-2020 10:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 2: Closed	Response satisfies query
Sep-11-2020 16:58:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	2 Nasal swab BARCODES for 1060 were put on separate sample



**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:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

				control forms during a shipment change. We show BP6V4F to be the correct one but lab has BP6V4H and is being held. Site scanned second barcode for query resolution. Either one is 1060 not diff sub
Sep-07-2020 14:37:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 2: Opened	DM1 LIMS Query: As per lab, sample ID is BP6V4H and not BP6V4F as reported here. Please check and correct the data, else clarify.
Aug-27-2020 11:13:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-25-2020 15:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-24-2020 22:14:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Lab query report says barcode is BP6V4H. Please verify SCF to confirm which barcode is correct.
Aug-11-2020 12:25:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP6V4F	Transcription Error
Aug-11-2020 12:20:30 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP6V56	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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				
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**5.b**

Date	Location	User	Value	Reason
Sep-11-2020 16:52:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP6V4H	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Sep-11-2020 16:52:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP6V4H	Initial Entry

090177e196ae3f94\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: 10831060

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

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

Date	Location	User	Value	Reason
Aug-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/6/2020 11:30	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Aug-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Aug-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f94\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:** 10831060

**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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-18-2020 19:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-17-2020 12:26:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Site has been in contact with this subject. Uns visits were offered and subject declined.
Aug-16-2020 19:19:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Subject reported:Temperature(102.1F) In the e-diary on 11 Aug, but no UNPL visit has occurred. Please can you confirm subject has been contacted? If so, report in UNPL log. Thanks
Aug-07-2020 18:06:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3f94\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:** 10831060

**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

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**1. Date of Visit**

Date	Location	User	Value	Reason
Oct-23-2020 15:08:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Oct-23-2020 15:08:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\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, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom:: FEVER Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: Au g/1 3/2 020	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
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090177e196ae3f94\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, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Aug/13/2020	Initial Entry
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2.b

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FATIGU E <b>Were fever or sys</b> YES <b>temic symptoms</b> Ongoin <b>present on the las</b> g? <b>t day the Subject</b> <b>Diary was comple</b> NO <b>ted?:</b>  Stop Date :  Au g/1 3/2 020	Initial Entry

090177e196ae3f94\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, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

2.b Symptom:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Aug/13/2020	Initial Entry

2.c

Date	Location	User	Value	Reason
Mar-12-2021 11:42:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEADACHE	New Information

090177e196ae3f94\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, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

			<p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b></p> <p>Ongoing? NO</p> <p>Stop Date : Au g/1 3/2 02 0</p>	
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> HE AD AC HE</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES</p>	Initial Entry

090177e196ae3f94\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, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Mar-12-2021 11:42:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Aug/13/2020	New Information
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

2.d

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

090177e196ae3f94\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, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

2.d Symptom:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</b> NO	Initial Entry

090177e196ae3f94\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, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA  <b>Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?:</b> NO	Initial Entry

090177e196ae3f94\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, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENE MUSCL E PAIN  <b>Were fever or sys NO</b> <b>temic symptoms</b> <b>present on the las</b> <b>t day the Subject</b> <b>Diary was comple</b> <b>ted?:</b>	Initial Entry

090177e196ae3f94\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, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED MU SCLE 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
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENERED JOINT P AIN  <b>Were fever or syst NO emic symptoms pr esent on the last d ay the Subject Dia ry was completed ?:</b>	Initial Entry

090177e196ae3f94\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

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Form Status: Data Complete, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOI NT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reactio RE n:: DN ES S	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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Form Status: Data Complete, Verified

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Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

			Were injection site reactions present on the last day the Subject Diary was completed?:	NO
--	--	--	---	----

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: SWELLING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3f94\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

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Form Status: Data Complete, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Mar-12-2021 11:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Oct-27-2020 02:56:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 13:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject is only Discontinued for the EOT as they did not get V2
Oct-26-2020 09:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	PDQ RQ1 : Thank you for the response. If subject is in follow up status and not discontinued kindly consider updating subject status to follow up at SUBSTAT visit.
Oct-23-2020 15:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	15SEP2020 PI decision to not do V2 due to SAE and unstable medical conditions. Subject did not discontinue and will be followed up for safety and data collection V3/Safety 22OCT2020
Oct-23-2020 05:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	PDQ : Subject is discontinued on 15SEP2020 and

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**Header Text:** c4591001  
**Visit:** V3\_MONTH1\_POSTVAX2\_L  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1083  
**Subject No:** 10831060  
**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:** ---  
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				visit 3 performed after discontinued date. Please clarify if V3 data entered as appropriate else update the data accordingly
Oct-23-2020 05:21:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	another query issued
Oct-23-2020 05:20:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Subject is discontinued on 15SEP2020 and visit 3 performed after discontinued date. Please clarify if V3 data entered as appropriate else update the data accordingly
Oct-22-2020 15:06:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/22/2020	Initial Entry

**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:** 10831060**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-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</b> Not Applicable	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	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-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.b**

Header Text: c4591001

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Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	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-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	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-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry

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**Header Text:** c4591001  
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**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1083 **Site Name:** (1083) Benchmark Research  
**Subject No:** 10831060 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:11

**2.d Symptom:**

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	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-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**2.e Symptom:**

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	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-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry

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Header Text: c4591001

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Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	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-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

2.g Symptom:

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	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-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry

090177e196ae3f94\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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	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-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reactio</b> Not <b>n::</b> App licab le	Initial Entry

090177e196ae3f94\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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

			Were injection site reactions present on the last day the Subject Diary was completed?:	Not Applicable
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> Not Applicable  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196ae3f94\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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> Not Applicable <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry

090177e196ae3f94\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:** 10831060

**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-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry



**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**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-22-2020 15:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-22-2020 15:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-22-2020 17:15:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 15:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-22-2020 15:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/22/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

Oct-22-2020 17:15:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP21WJ	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 17:15:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP21WJ	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-04-2020 14:24:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPHMT3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 14:24:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPHMT3	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-04-2020 14:25:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPHMT4	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 14:25:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPHMT4	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Mar-12-2021 01:36:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	data updated
Mar-10-2021 17:17:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	per CRA site to add data from this visit to previous covid illness visit A since the symptoms were not resolved. This visit was marked Erroneous were the reason on Audit Trail. There has been so much back and for on this. PLEASE ADVISE
Mar-10-2021 00:21:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	PDQ RQ1 : As per query response, CONVA visit with 5Jan21 is updated as COVID_B1 , however COVID_B visit is marked as erroneous. hence please check and update else clarify.
Mar-09-2021 18:25:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	see 05JAN2021 Convalescent visit
Mar-04-2021 05:02:11	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ:

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1083**Subject No:** 10831060**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS ONSET - 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

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		Convalescent visit is missing and 35+ days (90) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Dec-04-2020 16:54:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-04-2020 16:30:33 (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.
Dec-04-2020 16:30:33 (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.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Dec-04-2020 16:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/4/2020	Initial Entry
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**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Dec-04-2020 16:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/4/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Jan-06-2021 16:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Res olved:  Dec/17/2020	New Information
Dec-16-2020 01:10:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-15-2020 10:50:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	new symptom reported was added to symptom list please see YES to Diarrhea
Dec-15-2020 02:01:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: As per section 8.29 of completion guidelines, one illness visit period

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**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020  
**Form Version:** 10-Oct-2020 16:02  
**Site No:** 1083  
**Subject No:** 10831060  
**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

				lasts until all symptoms resolve. Please review and consider to move details from next visit into this visit.
Dec-14-2020 15:57:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original data is correct subject still has ongoing symptoms from this office visit and had a NEW potential illness symptom that was past the 7 day window from this covid illness visit
Dec-14-2020 10:34:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Next visit should be entered only if all the symptoms at this visit resolved. If resolved, please review and update the date of last symptom resolved as appropriate. If not, please move details from next visit into this visit.
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)			<b>Symptoms:</b> FEVER	
			<b>Symptom Present:</b> YES	

**4.a Symptoms:**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom NEW OR INCR</b> <b>s: EASED COUGH</b> <b>Symptom NO</b> <b>Present:</b>	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
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Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sympto NEW OR INCREA ms: SED SHORTNESS OF BREATH  Sympto NO m Pres ent:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

4.d

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILL S <b>Symptom Present</b> NO :	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCRE ASED MUSCLE PAIN <b>Symptom Present:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**4.g**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> YES	Initial Entry

**4.g Symptoms:**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Dec-14-2020 17:00:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> YES	New Information
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**4.h Symptoms:**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Dec-14-2020 17:00:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	New Information
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITIN G <b>Symptom Present:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**4.i Symptoms:**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Dec-04-2020 16:50:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-14-2020 09:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> Runny Nose	Initial Entry
Dec-14-2020 09:36:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b>	Transcription Error
Dec-04-2020 16:50:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> Runny Nose	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Dec-14-2020 10:53:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Closed	Discrepancy has been closed.
Dec-14-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b>	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

09:36:25 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	y: Runny No se	
Dec-14-2020 09:36:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Dec-14-2020 09:36:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entr</b> <b>y:</b>	Transcription Error
Dec-11-2020 16:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Opened	Special Characters: Verbatim Term contains embedded non-compliant characters.
Dec-11-2020 13:01:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Dec-08-2020 12:38:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Query is ambiguous
Dec-04-2020 22:28:02	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle	Query 1: Opened	Special Characters:

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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

(UTC-06:00) Central Time (US & Canada)		(b) (4)		Verbatim Term contains embedded non-compliant characters.
Dec-04-2020 16:50:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Runny Nose	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Date	Location	User	Value	Reason
Dec-04-2020 17:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

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*1. Actual Date of Collection:*

Date	Location	User	Value	Reason
Dec-16-2020 06:33:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-15-2020 17:16:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-15-2020 17:16:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/2/2020	Transcription Error
Dec-15-2020 13:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Per prior query response COVID-19 Date of Collection is 02Dec2020 Date of Diagnosis should match positive test date in Local or Central. Please update.
Dec-15-2020 12:08:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLIQUEY: Per prior query response COVID-19 Date of Collection is 02Dec2020 Date of Diagnosis should match positive test date in Local or Central. Please

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

				update.
Dec-04-2020 17:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/3/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-04-2020 17:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Dec-04-2020 17:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Dec-04-2020 17:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYND ROME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Dec-04-2020 17:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC T EST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Dec-04-2020 17:18:33	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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)	OTHER	
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**7. Test Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> POSITIVE	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Dec-11-2020 03:41:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-09-2020 14:34:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-09-2020 14:34:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : SARS-CoV-2 RNA CLIA CERTIFIED LAB	New Information
Dec-09-2020 00:07:37 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:	DM: Please consider to update 'Trade

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Central Time (US & Canada)			Open ed	Name Other, Specify' to indicate if test conducted in 'CLIA- certified lab' or 'ISO 15189 accredited lab' as per section 8.31.7 of completion guidelines. Please verify and update as appropriate.
Dec-08-2020 12:37:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: An swere d	Entered as instructed
Dec-07-2020 03:16:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4) [Redacted]	Query 1: Op ened	sars cov 2 rna is not indicated on the FDA cleared (including Emergency Use Authorization) diagnostic list and is not indicated as CLIA certified lab or ISO 15189 accredited lab . Please verify and update as appropriate. Otherwise,

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

				please provide clarification. (b) (4)
Dec-04-2020 17:19:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : SARS -CoV- 2 RN A	Transcription Error
Dec-04-2020 17:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : SARS -CoV- 2 RN A Det ected	Initial Entry

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**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:** 10831060**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
Dec-04-2020 16:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-04-2020 16:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-04-2020 16:55:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-04-2020 16:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Dec-04-2020 16:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Dec-04-2020 16:56:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**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:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

Dec-04-2020 16:56:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Self Swab not done but perfo rmed by PI	New Information
Dec-04-2020 16:54:13 (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.
Dec-04-2020 16:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Self Swab not done but perfo rmed by PI	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-04-2020 16:55:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error <b>(DELETED)</b>
Dec-04-2020 16:55:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error
Dec-04-2020 16:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BKN286	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-04-2020 16:55:59 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Transcription Error



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				<b>(DELETED)</b>
Dec-04-2020 16:55:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-04-2020 16:55:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Transcription Error
Dec-04-2020 16:55:11 (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.
Dec-04-2020 16:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BKN286	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**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:** 10831060**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
Dec-04-2020 16:54:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-04-2020 16:54:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-08-2020 12:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-06-2020 23:06:28 (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.
Dec-04-2020 16:54:55 (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.
Dec-04-2020 16:54:55 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)			Date of Collection:	
			Dec/4/2020	

**5.a**

Date	Location	User	Value	Reason
Dec-08-2020 12:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BKN286	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-08-2020 12:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BKN286	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Dec-04-2020 16:57:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Owner:</b> NCY ROOM <b>Occurrence of Visits or Contacts:</b>
--	--	--	--

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-04-2020 16:57:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Dec-04-2020 16:57:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b>	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICI AN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-04-2020 16:57:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
Dec-04-2020 16:57:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitio</b> URGEN <b>ner:</b> T CARE <b>Occurrence of Vi</b> NO <b>sits or Contacts:</b>	Initial Entry
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitio</b> URGEN <b>ner:</b> T CARE <b>Occurrence of Vi</b> <b>sits or Contacts:</b>	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-04-2020 16:57:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Dec-04-2020 16:57:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b>	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

*I.e Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-04-2020 16:57:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contact s:</i>  1	Initial Entry

***2. Other Type of Practitioner Specify:***

Date	Location	User	Value	Reason
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 Hr Covid Drive Thru Testi ng	Initial Entry

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

Date	Location	User	Value	Reason
Dec-04-2020 16:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**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:** 10831060**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
Dec-04-2020 16:57:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-04-2020 16:57:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Dec-04-2020 16:57:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Dec-04-2020 16:57:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Dec-04-2020 16:57:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Date	Location	User	Value	Reason
Dec-04-2020 16:57:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**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:** 10831060**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
Dec-14-2020 17:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-14-2020 16:58:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-14-2020 16:57:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of positive test result was 02Dec2020. Please confirm and update diagnosis date.
Dec-04-2020 17:13:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 IL LNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Dec-15-2020 12:07:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-15-2020 10:47:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Per source documentation collection date was 02DEC2020 if you want date of diagnosis to match date of collection original data is correct
Dec-15-2020 08:05:53	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLIQUERY:

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**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:** 10831060**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)		COVID-19 Date of Diagnosis is 02Dec2020 however Local positive COVID-19 test date was 03Dec2020. Date of Diagnosis should match positive test date in Local or Central. Please update or clarify.
Dec-14-2020 16:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Covid-19  Date of Diagnosis:  Dec/2/2020	New Information
Dec-14-2020 10:46:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-14-2020 09:30:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Covid-19  Date of Diagnosis:  Dec/3/2020	New Information
Dec-14-2020 09:29:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Dec-14-2020 09:29:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Covid-19  Date of Diagnosis:  Dec/4/2020	Changed Information
Dec-11-2020 15:37:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	CLIQUEY: Please remove Positive from diagnosis as should read as COVID-19.
Dec-11-2020 13:40:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Dec-11-2020 13:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Original Data is correct. Per progress note source, results were pending on 03DEC2020. Subject contacted site 04DEC2020 with results and sent site a screenshot for subject records.
Dec-11-2020 09:03:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CLIQUEY: COVID-19 Date of Diagnosis is 04Dec2020 however Local positive COVID-19 test date was 03Dec2020. Date

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled      **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
 Visit on Dec/04/2020  
**Form Version:** 06-Jul-2020 21:52      **Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1083      **Site Name:** (1083) Benchmark Research  
**Subject No:** 10831060      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 10:11

				of Diagnosis should match positive test date in Local or Central. Please update or clarify.
Dec-04-2020 17:15:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Positive Covid-19  Date of Diagnosis:  Dec/4/2020	New Information
Dec-04-2020 17:13:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-14-2020 10:46:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-14-2020 09:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-14-2020 07:14:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: COVID-19 Date of Diagnosis is 04Dec2020 however Local positive COVID-19 test date was 03Dec2020. Date of Diagnosis

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

				should match positive test date in Local or Central. Please update or clarify.
Dec-04-2020 17:13:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 1	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-04-2020 17:14:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Dec-04-2020 17:14:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Dec-04-2020 17:14:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-04-2020 17:14:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**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:** 10831060**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
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Appl icable <b>Test::</b> Not Appl icable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020  
**Form Version:** 30-Jul-2020 21:27  
**Site No:** 1083  
**Subject No:** 10831060  
**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.b**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - 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

Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - 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

Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - 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

Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - 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

Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - 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

Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**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:** 10831060**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
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Appl icable <b>Test::</b> Not Appl icable	Initial Entry



**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020  
**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1083  
**Subject No:** 10831060  
**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

			<b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	
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**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020  
**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1083  
**Subject No:** 10831060  
**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

Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.b**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020  
**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1083  
**Subject No:** 10831060  
**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.b Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020  
**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1083  
**Subject No:** 10831060  
**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.c Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020  
**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:** 10831060  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:11

**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020  
**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1083  
**Subject No:** 10831060  
**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.e Sponsor ID:**

Date	Location	User	Value	Reason
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**5.e Test:**

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**5.e Result:**

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Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
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**5.e LNMT**

Date	Location	User	Value	Reason
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**5.f**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020  
**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:** 10831060  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:11

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Test:**

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**5.f Result:**

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**5.f Not Done:**

Date	Location	User	Value	Reason
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**5.f LNMT**

Date	Location	User	Value	Reason
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**5.g**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020  
**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:** 10831060  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:11

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020  
**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:** 10831060  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:11

**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
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**5.i Result:**

Date	Location	User	Value	Reason
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**5.i Not Done:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/04/2020  
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**Site No:** 1083  
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**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
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**Generated Time (GMT):** 29-Mar-2021 10:11

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
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**5.j Test:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j Not Done:**

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**5.j LNMT**

Date	Location	User	Value	Reason
Dec-04-2020 17:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**Form:** VITAL SIGNS - COVID - Audit Trail

**Form Version:** 30-Jul-2020 21:27

**Form Status:**

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Date	Location	User	Value	Reason
Dec-04-2020 17:02:42 (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 Dec/04/2020

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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

*1. Date:*

Date	Location	User	Value	Reason
Dec-04-2020 17:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/4/2020	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Dec-04-2020 17:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 14 2 <b>Diastolic::</b> 86 <b>Respiratory Rate in res</b> 14 <b>pitations/minute:</b> <b>Heart Rate in beats/min</b> 69 <b>ute:</b>	Initial Entry

*2.a Record Identifier:*

Date	Location	User	Value	Reason
Dec-04-2020 17:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

*2.a Systolic:*

Date	Location	User	Value	Reason
Dec-06-2020 22:18:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-04-2020 17:03:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per source PI assessed NCS

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Dec-04-2020 17:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 142 is outside of Normal Range 90 - 140.
Dec-04-2020 17:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 142	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Dec-04-2020 17:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 86	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Dec-04-2020 17:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 14	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Dec-04-2020 17:02:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 69	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**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:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Dec-04-2020 16:59:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-04-2020 16:59:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> Not Applicable <b>Oxygen Saturation:</b> Not Applicable	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-04-2020 16:59:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Dec-04-2020 16:59:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Dec-04-2020 16:59:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Dec-04-2020 16:59:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Dec-04-2020 16:59:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020**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:** 10831060**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
Dec-04-2020 16:58:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Dec-04-2020 16:58:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-04-2020 16:58:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Dec-04-2020 16:58:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Dec-04-2020 16:58:22 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				
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**6. Ongoing?**

Date	Location	User	Value	Reason
Dec-04-2020 16:58:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Dec/04/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-04-2020 16:58:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Dec-04-2020 16:58:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Dec-04-2020 16:58:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Dec-04-2020 16:58:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Dec-16-2020 03:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Deleted	Query is invalid or does not apply
Dec-16-2020 02:58:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Dec-15-2020 22:44:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Dec-15-2020 11:53:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Changed data per query
Dec-15-2020 11:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: 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.
Dec-15-2020 10:52:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Correct per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-15-2020 08:32:44 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Date of Visit is completed but

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1083**Subject No:** 10831060**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS ONSET - 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

Time (US & Canada)				Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-14-2020 21:13:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	DM: Erroneous visit is marked. However, data is present on SOD, SELF SWAB, SWAB PFE, HLTHCARE, ILL POTEN, VITALS COV forms. Kindly consider to clear the data and add form level comment by selecting Not Applicable option on mentioned forms, else clarify.
Dec-14-2020 17:05:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: 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.
Dec-14-2020 16:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

				visit.
Dec-11-2020 13:44:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Dec-11-2020 13:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: 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.
Dec-11-2020 13:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-11-2020 13:36:52 (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.
Dec-11-2020 13:36:52 (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.

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

Dec-11-2020 13:36:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/11/2020	Initial Entry
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**2. Erroneous Visit**

Date	Location	User	Value	Reason
Dec-14-2020 17:07:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-14-2020 16:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Dec-14-2020 16:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry
Dec-14-2020 16:43:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Visit will need to be marked as erroneous because COVID A visit has not been resolved prior to start of new COVID visit. All symptoms reported at this visit will need to be moved to COVID A

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

Date	Location	User	Value	Reason
Dec-11-2020 13:36:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_B	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**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
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/11/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/10/2020	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				
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**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry
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**4.a Symptoms:**

Date	Location	User	Value	Reason
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCR <b>s:</b> EASED COUG H	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

			<b>Symptom Not Applicable Present:</b>	
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom NEW OR INCR s:</b> EASED COUGH <b>Symptom Present:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom NEW OR INCR s:</b> EASED COUGH <b>Symptom NO Present:</b>	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**4.b Symptoms:**

Date	Location	User	Value	Reason
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED CO UGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW OR INCREA <b>oms:</b> SED SHORTNESS OF BREATH <b>Sympt</b> Not Applicable <b>om Pre</b> <b>sent:</b>	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW OR INCREA	per CRA site to add data from this

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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

Time (US & Canada)			<b>oms:</b> SED SHORTNESS OF BREATH <b>Symptom Present:</b>	visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom Present:</b> NEW OR INCREASED SED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11**4.c Symptoms:**

Date	Location	User	Value	Reason
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Pres</b> Not Applic <b>ent:</b> able	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILL S <b>Symptom Present</b> :	per CRA site to add data from this visit to previous covid illness visit since the

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020  
**Form Version:** 10-Dec-2020 02:29  
**Site No:** 1083  
**Subject No:** 10831060  
**Generated By:** (b) (4)  
**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

				symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILL S <b>Symptom Present</b> NO :	Initial Entry

**4.d Symptoms:**

Date	Location	User	Value	Reason
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom Present:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom Present:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom Present:</b> NO	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
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Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MU SCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympto</b> NEW LOSS OF <b>ms:</b> TASTE OR SME LL <b>Sympto</b> Not Applicable <b>m Presen</b> <b>t:</b>	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympto</b> NEW LOSS OF	per CRA site to add data from this

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

Time (US & Canada)			<b>ms:</b> TASTE OR SME LL <b>Symptom Present:</b>	visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom Present:</b> NEW LOSS OF TASTE OR SME LL <b>Symptom Present:</b> NO	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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4.f Symptoms:

Date	Location	User	Value	Reason
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCRE ASED SORE TH ROAT <b>Symptom Present:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCRE	per CRA site to add data from this

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

Time (US & Canada)			<b>ms:</b> ASED SORE TH ROAT <b>Symptom Present:</b>	visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>ms:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**4.g Symptoms:**

Date	Location	User	Value	Reason
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SOR E THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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4.h				
Date	Location	User	Value	Reason
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRH EA <b>Symptom Present:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRH EA <b>Symptom Present:</b> YES	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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**4.h Symptoms:**

Date	Location	User	Value	Reason
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Dec-15-2020 19:29:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-14-2020 17:12:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-14-2020 16:42:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per Protocol 8.29, this COVID Illness Visit B will have to be deleted and diarrhea will have to be moved to COVID A because there are

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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

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**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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				still symptoms ongoing and a new COVID visit cannot be added until all previous symptoms resolved.
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITIN G <b>Symptom Present:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITIN G <b>Symptom Present:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITIN G <b>Symptom Present:</b> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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**Form Version:** 10-Dec-2020 02:29

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**4.i Symptoms:**

Date	Location	User	Value	Reason
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Dec-15-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	per CRA site to add data from this visit to previous covid illness visit since the symptoms were not resolved. This visit was marked Erroneous
Dec-11-2020 13:38:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Trade Name:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Date	Location	User	Value	Reason
Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Dec-11-2020 13:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**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
Dec-15-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-15-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-15-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:22:51 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Transcription Error

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

Time (US & Canada)				
Dec-11-2020 13:46:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-11-2020 13:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: 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.
Dec-11-2020 13:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-11-2020 13:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Self swab not done but obtained by PI at this office visit
Dec-11-2020 13:42:05 (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.
Dec-11-2020 13:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Collection:  Dec/11/2020	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

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

**Site No:** 1083

**Subject No:** 10831060

**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
Dec-15-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:25:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:46:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-11-2020 13:46:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Self swab not done but obtained by PI at this office visit	Transcription Error
Dec-11-2020 13:46:18 (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.
Dec-11-2020 13:46:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Self swab not done but obtained by PI at this office visit	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**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
Dec-15-2020 11:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-14-2020 17:05:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:44:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-15-2020 11:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-14-2020 17:05:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:44:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-15-2020 11:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-14-2020 17:05:07 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

Time (US & Canada)				
Dec-14-2020 17:05:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-14-2020 17:04:55 (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.
Dec-11-2020 15:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-11-2020 13:44:00 (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.
Dec-11-2020 13:44:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/11/2020	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Dec-15-2020 11:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

Dec-15-2020 11:28:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error
Dec-15-2020 11:28:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRCJ7H	Transcription Error
Dec-14-2020 17:11:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRCJ7H	New Information (DELETED)
Dec-14-2020 17:05:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRCJ7H	Transcription Error
Dec-14-2020 17:04:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRCJ7H	Transcription Error (DELETED)
Dec-11-2020 15:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRCJ7H	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-15-2020 19:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-15-2020 11:28:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-15-2020 11:28:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRCJ7H	Transcription Error
Dec-14-2020 17:11:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRCJ7H	New Information (DELETED)
Dec-14-2020 17:05:41	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**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)	BRCJ7H	Error
Dec-14-2020 17:04:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRCJ7H	Transcription Error <b>(DELETED)</b>
Dec-14-2020 17:04:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-14-2020 16:45:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Site swab will need to be moved to "REPEAT SWAB – New Unscheduled Visit" because no new COVID visit should have started without resolution of COVID A.
Dec-11-2020 15:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRCJ7H	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> Not Applicable	Initial Entry
Dec-15-2020 11:30:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b>	Transcription Error
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:30:53 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*1.b*

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGE NCY ROOM <b>Occurrence of Visits or Contacts:</b> Not Applicable	Initial Entry
Dec-15-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGE NCY ROOM <b>Occurrence of Visits or Contacts:</b>	Transcription Error
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGE NCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**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
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***I.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.c***

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Prac</b> PRIMARY <b>itioner:</b> CARE PHY SICIAN <b>Occurrence</b> Not Applica <b>of Visits or C</b> ble <b>ontacts:</b>	Initial Entry
Dec-15-2020 11:31:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Prac</b> PRIMARY <b>itioner:</b> CARE PHY SICIAN <b>Occurrence</b> <b>of Visits or C</b> <b>ontacts:</b>	Transcription Error

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
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***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:31:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> Not Applicable	Initial Entry
Dec-15-2020 11:31:59	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**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)	<b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b>	Error
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:31:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

			<b>Occurrence of Visits or Contacts:</b> Not Applicable	
Dec-15-2020 11:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b>	Transcription Error
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

*I.f*

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> Not Applicable	Initial Entry
Dec-15-2020 11:32:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b>	Transcription Error
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:32:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***2. Other Type of Practitioner Specify:***

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-15-2020 11:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:29:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:44:41	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**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)

NO

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**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
Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Date	Location	User	Value	Reason
Dec-11-2020 13:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**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
Dec-15-2020 11:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLN ESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Dec-15-2020 11:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-15-2020 11:52:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:52:47 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				
Dec-11-2020 13:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 1	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**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
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Appl icable <b>Test::</b> Not Appl icable	Initial Entry

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020  
**Form Version:** 30-Jul-2020 21:27  
**Site No:** 1083  
**Subject No:** 10831060  
**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			<b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	
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**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020  
**Form Version:** 30-Jul-2020 21:27  
**Site No:** 1083  
**Subject No:** 10831060  
**Generated By:** (b) (4)  
**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.b**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - 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

Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Not Done:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - 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

Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
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Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - 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

Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Form Version:** 30-Jul-2020 21:27

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**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

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

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
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**5.e LNMT**

Date	Location	User	Value	Reason
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**5.f**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - 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

Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
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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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
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Visit on Dec/11/2020

**Form Version:** 30-Jul-2020 21:27

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**Subject No:** 10831060

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**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

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

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**Subject Initials:** ---

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

Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Not Done:**

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**5.g LNMT**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**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
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Appl icable <b>Test::</b> Not Appl icable	Initial Entry

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020  
**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1083  
**Subject No:** 10831060  
**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

			<b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	
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**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020  
**Form Version:** 30-Jul-2020 21:28  
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**Subject No:** 10831060  
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**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

Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.b**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

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**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1083  
**Subject No:** 10831060  
**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.b Sponsor ID:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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Visit on Dec/11/2020

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**Site No:** 1083

**Subject No:** 10831060

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**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

Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1083  
**Subject No:** 10831060  
**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen, Verified  
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**Generated Time (GMT):** 29-Mar-2021 10:11

**5.c Sponsor ID:**

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**5.c Test:**

Date	Location	User	Value	Reason
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**5.c Result:**

Date	Location	User	Value	Reason
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**5.c Not Done:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
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**5.d**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

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Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**5.d LNMT**

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**5.e**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

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Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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Date	Location	User	Value	Reason
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**5.e LNMT**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Not Done:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f LNMT**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020  
**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1083  
**Subject No:** 10831060  
**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.h Sponsor ID:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Not Done:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h LNMT**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1083

**Subject No:** 10831060

**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

Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/11/2020  
**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1083  
**Subject No:** 10831060  
**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.j Sponsor ID:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j Not Done:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**Form:** VITAL SIGNS - COVID - Audit Trail

**Form Version:** 30-Jul-2020 21:27

**Form Status:**

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Date	Location	User	Value	Reason
Dec-11-2020 13:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

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*1. Date:*

Date	Location	User	Value	Reason
Dec-15-2020 11:50:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:38:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/11/2020	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Dec-15-2020 11:50:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier: 1</b> : <b>Systolic::</b> Not Ap plicabl e <b>Diastolic::</b> Not Ap plicabl e <b>Respiratory Rate i</b> Not Ap <b>n respirations/min</b> plicabl <b>ute:</b> e <b>Heart Rate in beat</b> Not Ap <b>s/minute:</b> plicabl e	Initial Entry
Dec-15-2020 11:39:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> <b>Diastolic::</b>	Transcription Error

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11

Dec-15-2020 11:50:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:39:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 77	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Dec-15-2020 11:50:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:39:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 64	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Dec-15-2020 11:50:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-15-2020 11:39:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-11-2020 13:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 14	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Date:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> Not Applicable <b>Oxygen Saturation:</b> Not Applicable	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Dec-11-2020 13:49:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Dec-11-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Dec-11-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Dec-11-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020**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:** 10831060**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
Dec-11-2020 13:50:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Dec-11-2020 13:50:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Dec-11-2020 13:50:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 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
Dec-11-2020 13:50:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Dec-11-2020 13:50:28 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				
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**6. Ongoing?**

Date	Location	User	Value	Reason
Dec-11-2020 13:50:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Dec/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-11-2020 13:50:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Dec-11-2020 13:50:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Dec-11-2020 13:50:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Dec-11-2020 13:50:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/05/2021

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-06-2021 16:32:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/5/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 10:19:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	data updated
Mar-11-2021 06:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Correct
Mar-11-2021 06:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Correct
Mar-11-2021 04:16:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opene d	DM2: Please confirm if this visit is corresponding to 'COVID_A' Covid illness visit. Thank you.
Mar-10-2021 17:16:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	per CRA site to add data from this visit to previous covid illness visit A since the symptoms were not resolved. This visit was marked Erroneous were the

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/05/2021**Form Version:** 22-Apr-2020 21:04**Site No:** 1083**Subject No:** 10831060**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - 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

				reason on Audit Trail. There has been so much back and for on this. PLEASE ADVISE
Mar-10-2021 00:23:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM 1: Thanks for response. However, COVID_B is still marked as Erroneous visit but COV CONV (COVID_B1) is completed. Please review and update the data as appropriate. Else, clarify.
Mar-09-2021 12:49:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Please see 11DEC2020 Covid Illnes Visit COVID B that correlates with COVID_B1 Convalescent Visit
Mar-04-2021 01:41:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Convalescent visit - COVID_B1 has been updated, however corresponding COVID illness visit - COVID_B is marked as Erroneous. Please review and update this CONVALESCENT visit as appropriate, else clarify further. Thank you.
Mar-03-2021 16:57:57	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_B1	New Information

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/05/2021**Form Version:** 22-Apr-2020 21:04**Site No:** 1083**Subject No:** 10831060**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - 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

(UTC-06:00) Central Time (US & Canada)				
Jan-11-2021 13:15:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-11-2021 10:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-11-2021 10:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	New Information
Jan-11-2021 06:08:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Please review and correct or clarify as corresponding COVID illness visit (COVID_B) is marked erroneous, but Subject has completed Convalescent visit (COVID_B1).
Jan-08-2021 15:01:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Query is ambiguous
Jan-06-2021 22:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Subject has completed Convalescent visit (COVID_B1), however corresponding COVID illness visit (COVID_B) is marked erroneous. Please review and update the details as appropriate, else clarify with

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/05/2021

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

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

				comment. Thank you.
Jan-06-2021 16:32:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_B1	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/05/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1083**Subject No:** 10831060**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - 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. Data Origin**

Date	Location	User	Value	Reason
Jan-06-2021 16:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-06-2021 16:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-06-2021 16:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-06-2021 16:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-06-2021 16:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/05/2021

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Jan-06-2021 16:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRCJ9L	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-06-2021 16:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRCJ9L	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-06-2021 16:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM3M47	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-06-2021 16:35:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM3M47	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-06-2021 16:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM3M48	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-06-2021 16:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM3M48	Initial Entry

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**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Aug/07/2020**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:** 10831060**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
Aug-25-2020 19:12:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-24-2020 11:00:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was initially contacted due to report of fever on eDiary. The date of the SAE was date the condition worsened and met the criteria for an SAE due to hospitalization
Aug-22-2020 19:40:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery: response not satisfactory. subject SAE began on 15 Aug and in the e-diary, the events that triggered the call began on 11 Aug. Please confirm the date the SAE began and the reason subject was initially called
Aug-20-2020 14:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Related to SAE
Aug-19-2020 19:46:48 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: UNPL: 07 Aug: Please can

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Aug/07/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				you confirm why the subject was called at date when the severe temperature in e-diary began on 11 Aug? Was there resolution over the phone?
Aug-17-2020 15:35:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/7/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Aug/07/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Assessments*

Date	Location	User	Value	Reason
Aug-17-2020 15:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 15:36:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-17-2020 15:36:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Aug/07/2020**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Aug-17-2020 15:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Aug-17-2020 15:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Aug/7/2020  Contact Outcome:  VISIT ARRANGED, BU T NOT ATTENDED	Initial Entry

**3. Comments:**

Date	Location	User	Value	Reason
Aug-19-2020 08:26:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-18-2020 12:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Aug-18-2020 12:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Site has been in contact with this subject. Uns visits were offered and subject declined	Initial Entry
Aug-18-2020 11:56:46 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	To close the DM queries, please

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Aug/07/2020

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME - UNPLANNED - 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

Time (US & Canada)

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

add comment here- "Site has been in contact with this subject. Uns visits were offered and subject declined." per your previous response.

**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on Aug/08/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Aug-25-2020 19:12:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-24-2020 11:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was initially contacted due to report of fever on eDiary. The date of the SAE was date the condition worsened and met the criteria for an SAE due to hospitalization
Aug-22-2020 19:40:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery: response not satisfactory. subject SAE began on 15 Aug and in the e-diary, the events that triggered the call began on 11 Aug. Please confirm the date the SAE began and the reason subject was initially called
Aug-20-2020 14:45:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Related to SAE
Aug-19-2020 19:46:35 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: UNPL: 08 Aug: Please can

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on Aug/08/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				you confirm why the subject was called at date when the severe temperature in e-diary began on 11 Aug? Was there resolution over the phone?
Aug-17-2020 15:37:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/8/2020	Initial Entry



**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on Aug/08/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Assessments*

Date	Location	User	Value	Reason
Aug-17-2020 15:37:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 15:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-17-2020 15:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 2 - Unscheduled Visit on Aug/08/2020**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Aug-17-2020 15:37:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Aug-17-2020 15:37:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Aug/8/2020  Contact Outcome:  VISIT ARRANGED, BU T NOT ATTENDED	Initial Entry

**3. Comments:**

Date	Location	User	Value	Reason
Aug-18-2020 12:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Site has been in contact with this subject. Uns visits were o ffered and subject declined	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on Aug/11/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-17-2020 15:51:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on Aug/11/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Assessments*

Date	Location	User	Value	Reason
Aug-17-2020 15:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 15:51:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-17-2020 15:51:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 3 - Unscheduled Visit on Aug/11/2020**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Aug-17-2020 15:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Aug-17-2020 15:51:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Aug/11/2020  Contact Outcome:  VISIT ARRANGED, BUT NOT ATTENDED	Initial Entry

**3. Comments:**

Date	Location	User	Value	Reason
Aug-18-2020 12:23:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Site has been in contact with this subject. Uns visits were offered and subject declined	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 4 - Unscheduled Visit on  
Aug/12/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-17-2020 15:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/12/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 4 - Unscheduled Visit on Aug/12/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Assessments*

Date	Location	User	Value	Reason
Aug-17-2020 15:52:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 15:51:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-17-2020 15:51:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 4 - Unscheduled Visit on Aug/12/2020**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Aug-17-2020 15:52:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Aug-17-2020 15:52:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Aug/12/2020  Contact Outcome:  VISIT ARRANGED, BUT NOT ATTENDED	Initial Entry

**3. Comments:**

Date	Location	User	Value	Reason
Aug-18-2020 12:23:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Site has been in contact with this subject. Uns visits were offered and subject declined	Initial Entry



**Header Text:** c4591001

**Visit:** Unplanned 5 - Unscheduled Visit on Aug/13/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Aug-25-2020 19:12:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-24-2020 11:01:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was initially contacted due to report of fever on eDiary. The date of the SAE was date the condition worsened and met the criteria for an SAE due to hospitalization
Aug-22-2020 19:40:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery: response not satisfactory. subject SAE began on 15 Aug and in the e-diary, the events that triggered the call began on 11 Aug. Please confirm the date the SAE began and the reason subject was initially called
Aug-20-2020 14:46:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Related to SAE
Aug-19-2020 19:45:51 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: UNPL: 13 Aug: Please can

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 5 - Unscheduled Visit on Aug/13/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				you confirm why the subject was called at date when the severe temperature in e-diary began on 11 Aug, and reduced on 12 Aug? Was there resolution over the phone?
Aug-17-2020 15:52:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 5 - Unscheduled Visit on Aug/13/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Assessments*

Date	Location	User	Value	Reason
Aug-17-2020 15:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 15:52:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-17-2020 15:52:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 5 - Unscheduled Visit on Aug/13/2020**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Aug-17-2020 15:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Aug-17-2020 15:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Aug/13/2020  Contact Outcome:  VISIT ARRANGED, BUT NOT ATTENDED	Initial Entry

**3. Comments:**

Date	Location	User	Value	Reason
Aug-18-2020 12:23:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Site has been in contact with this subject. Uns visits were offered and subject declined	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on Aug/14/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Aug-25-2020 19:12:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-24-2020 11:01:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was initially contacted due to report of fever on eDiary. The date of the SAE was date the condition worsened and met the criteria for an SAE due to hospitalization
Aug-22-2020 19:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery: response not satisfactory. subject SAE began on 15 Aug and in the e-diary, the events that triggered the call began on 11 Aug. Please confirm the date the SAE began and the reason subject was initially called
Aug-20-2020 14:46:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Related to SAE
Aug-19-2020 19:45:32 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: UNPL: 14 Aug: Please can

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on Aug/14/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				you confirm why the subject was called at date when the severe temperature in e-diary began on 11 Aug, and reduced on 12 Aug?Was there resolution over the phone?
Aug-17-2020 15:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/14/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on Aug/14/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Assessments*

Date	Location	User	Value	Reason
Aug-17-2020 15:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 15:53:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-17-2020 15:53:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on Aug/14/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Contact Type:**

Date	Location	User	Value	Reason
Aug-17-2020 15:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Aug-17-2020 15:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Aug/14/2020  Contact Outcome:  VISIT NOT ARRANGED , UNABLE TO ATTEND	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on Aug/15/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Aug-25-2020 19:13:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-24-2020 11:00:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject was initially contacted due to report of fever on eDiary. The date of the SAE was date the condition worsened and met the criteria for an SAE due to hospitalization
Aug-22-2020 19:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery: response not satisfactory. subject SAE began on 15 Aug and in the e-diary, the events that triggered the call began on 11 Aug. Please confirm the date the SAE began and the reason subject was initially called
Aug-20-2020 14:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Related to SAE
Aug-19-2020 19:45:09 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: UNPL: 15 Aug: Please can

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on Aug/15/2020

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Time (US & Canada)				you confirm why the subject was called at date when the severe temperature in e-diary began on 11 Aug, and reduced on 12 Aug? Was there resolution over the phone?
Aug-17-2020 15:53:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/15/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on Aug/15/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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*I. Assessments*

Date	Location	User	Value	Reason
Aug-17-2020 15:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 15:53:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-17-2020 15:53:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 7 - Unscheduled Visit on Aug/15/2020**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Aug-17-2020 15:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Aug-17-2020 15:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-17-2020 15:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Aug/15/2020  Contact Outcome:  VISIT NOT ARRANGED, UNABLE TO ATTEND	Transcription Error
Aug-17-2020 15:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Contact" is missing.
Aug-17-2020 15:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Contact Outcome:  VISIT NOT ARRANGED, UNABLE TO ATTEND	Initial Entry

**3. Comments:**

**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on Aug/15/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Date	Location	User	Value	Reason
Aug-24-2020 21:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Aug-21-2020 12:54:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject declined to come in due to increased abdominal pain and then now in SAE status as subject has been hospitalized
Aug-21-2020 04:33:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Response not satisfactory:Subject outcome states subject declined the visit. Subject has since expressed increased abdominal pain. can you confirm if a visit will be needed? Subject has consented to comply with study procedures. Is this still the case?
Aug-20-2020 14:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Related to SAE
Aug-19-2020 20:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	ClinQuery: Subject outcome states subject has declined the visit. Subject has since expressed increased abdominal pain. Please can you confirm if a visit

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 7 - Unscheduled Visit on Aug/15/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1083**Subject No:** 10831060**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - UNPLANNED - 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

				will be needed? Subject has consented to comply with study procedures. Is this still the case?
Aug-19-2020 14:28:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-18-2020 12:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Aug-18-2020 12:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Site has been in contact with this subject. Uns visits were offered and subject declined	Initial Entry
Aug-18-2020 11:58:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	For each unplanned contact entry, add comment as to why subject did not attend visit.

**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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

Date	Location	User	Value	Reason
Nov-13-2020 14:19:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020 12:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-13-2020 12:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/14/2020	New Information
Nov-10-2020 20:43:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The discontinuation date of 15SEP2020 should be relative to the AE causing the the withdrawal of the study vaccine, AE start 14AUG2020 and end 24AUG2020 (date should not be after the AE ended). Please adjust Discontinuation date.
Sep-24-2020 15:22:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

***2. Phase of Disposition:***

090177e196ae3f94\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: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-24-2020 15:22:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-09-2020 14:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-08-2020 17:30:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Closed	Response satisfies query
Oct-08-2020 14:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original Data is correct and entered correctly as this is End of Treatment page not the FUP. Subject is not being discontinued in the study. AE was recorded per previous query that the subject is continuing in the study without completing Vax 2/study IP
Oct-08-2020 14:36:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Oct-06-2020 14:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Opened	CLINQUERY: Please review the Adverse Events under the Log tab

090177e196ae3f94\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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

				and select which led to treatment discontinuation. At least one AE needs to have the 'Latest Action Taken with Study Treatment' field completed as DRUG WITHDRAWN to match to this entry
Oct-05-2020 06:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM1: Thank you for the response however please consider to update an item level comment to clarify the reason further.
Oct-02-2020 00:32:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Similar issue added in DM Q & A tracker; once response received will take action accordingly on both.
Oct-01-2020 13:50:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	this page is the End of Treatment not Follow-up Visit per Sec 8.55 in the eCRF guidelines. And that the subject is continuing in the study without Vaccination 2.
Oct-01-2020 13:48:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Response does not satisfy query

090177e196ae3f94\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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Oct-01-2020 13:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Site will screenshot this AE Audit trail and contact CRA for best way to answer this query
Sep-29-2020 19:15:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-29-2020 02:00:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opene d	DM : Thanks for the response, however there is no Adverse Event recorded with "Did the adverse event cause the subject to be discontinued from the study' reported as "YES", please review and update appropriately, else clarify.
Sep-28-2020 14:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Sep-28-2020 14:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.

090177e196ae3f94\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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Sep-28-2020 14:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-28-2020 14:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ADVERSE EVENT	New Information
Sep-26-2020 20:36:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: PHYSICIAN DECISION: Please can you confirm the reason of PI discontinuing the subject? If this is in relation to an AE please update as appropriate. Thanks
Sep-24-2020 15:22:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PHYSICIAN DECISION	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB 1 -  
Unscheduled Visit on Dec/11/2020

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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**1. Date of Visit**

Date	Location	User	Value	Reason
Dec-14-2020 16:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/11/2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-14-2020 16:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_BR1	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_REPEAT\_SWAB 1 -  
Unscheduled Visit on Dec/11/2020**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB -  
eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**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
Dec-14-2020 16:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-14-2020 16:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-14-2020 16:54:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-14-2020 16:54:36 (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.
Dec-14-2020 16:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB 1 -  
Unscheduled Visit on Dec/11/2020

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

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

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

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Dec-14-2020 16:54:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRCJ7H	Initial Entry
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**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-14-2020 16:54:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRCJ7H	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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Date	Location	User	Value	Reason
Aug-18-2020 18:20:52 (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:** 10831060

**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

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Date	Location	User	Value	Reason
Sep-04-2020 15:23:14 (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:** 10831060

**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

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Date	Location	User	Value	Reason
Sep-18-2020 17:49:50 (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:** 10831060

**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

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Date	Location	User	Value	Reason
Sep-18-2020 17:54:31 (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:** 10831060

**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

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Date	Location	User	Value	Reason
Sep-21-2020 16:49:19 (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:** 10831060

**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

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Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (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:** 10831060

**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

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Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**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

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Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (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:** 10831060

**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

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Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (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:** 10831060

**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

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Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (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:** 10831060

**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

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Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (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:** 10831060**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - 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. Category:**

Date	Location	User	Value	Reason
Sep-02-2020 07:20:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	reissued on AE term field
Sep-01-2020 06:46:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: For AER#2020319554 POST-OP ILEUS(onset date:14Aug2020)was reported as new serious event in Safety database but was not recorded in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:***(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-22-2020 08:33:50 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - 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

Time (US & Canada)				
Sep-21-2020 15:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Sep-21-2020 14:32:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Opened	please submit a follow-up SAE form to update accordingly.
Sep-18-2020 17:08:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Site will make them seperate AE's and once PI signs off crc will enter into EDC
Sep-18-2020 17:06:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	CRC inadvertently thought she was updating new follup up AE terms on the SAE form in the section where is makes them new SAEs. Site will send SAE follow up update and the original SAE of worsening of Abdominal pain will be the one SAE the others AE's
Sep-16-2020 14:09:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	SAE report faxed on 15Sep2020 updated SAE term to Divertocular Abscess/inflammation "Phlegmom". Please consider updating this as the AE term instead of "worsening of abdominal pain" or add AE to enter

090177e196ae3f94\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: 10831060

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

				Divertocular Abscess/inflammation "Phlegmom" separately.
Sep-15-2020 11:11:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	CLINICAL If the ruptured diverticulum is the underlying diagnosis for the worsening abd pain, please submit a follow-up SAE form to update accordingly
Sep-11-2020 17:11:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	site will make this an AE
Sep-10-2020 11:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLINICAL SAE narrative updated with pathological diagnosis of ruptured diverticulum. Please enter this serious adverse event in case report form.
Sep-07-2020 22:55:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	event recorded as AE#2
Sep-04-2020 15:23:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Sep-04-2020 05:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON 1: As of today, the event POST-OP Ileus is still missing in AE CRF. Please confirm and update accordingly.

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - 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-03-2020 06:51:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candiate	SAE RECON: to monitor data entry of event
Sep-02-2020 15:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Site will update accordingly
Sep-02-2020 09:26:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 2: Closed	Response satisfies query
Sep-02-2020 07:19:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: For AER#2020319554 POST-OP ILEUS(onset date:14Aug2020)was reported as new serious event in Safety database but was not recorded in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Aug-27-2020 16:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Site received new medical records 8/27/2020. Site will be reviewing them with PI and and follow up report #3 will be sent
Aug-27-2020 14:13:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 2: Reissued:Opened	Response not satisfactory. Please can you provide an update regarding clinical course including the surgery? Thanks

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Aug-27-2020 12:12:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Aug-27-2020 12:12:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Worsening of Abdominal Pain	New Information
Aug-26-2020 02:58:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 2: Opened	Please can you provide an update regarding clinical course including the surgery? Thanks
Aug-24-2020 18:52:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-20-2020 14:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Follow up report was faxed on 19-AUG-2020 with the information requested
Aug-19-2020 19:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please can you provide an update on the case to understand the clinical course of this AE including work up/diagnostic procedures performed. thanks
Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Increased Abdominal Pain	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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Aug-28-2020 05:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	query resolved
Aug-27-2020 12:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-27-2020 12:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/14/2020 00:00	New Information
Aug-26-2020 03:15:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER# 2020319554
Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/15/2020 00:00	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Aug/24/2020 11:32	New Information
Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-22-2020 19:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-21-2020 17:33:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	PI and medical monitor had a discussion and PI wil make this an

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				SAE as he does not want to downgrade the Toxicity grade and feels this was a co-finding that was lifethreatening directly related to the underlying condition Ruptured Diverticulum
Dec-17-2020 13:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL Worsening Abdominal pain AE has Grade 4 severity, which is life-threatening. Please review if this (non-SAE) abdominal pain was grade 4.
Dec-09-2020 16:32:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	clin: CRA will f/u
Dec-09-2020 14:43:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per PI original value is correct
Dec-09-2020 08:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	clinical: per protocol grade 4 toxicity meets definition for SAE reporting, pls either submit SAE form to sponsor immediately or advise if initial grading was an error and update CRF accordingly. Thanks

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Aug-23-2020 02:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-20-2020 14:42:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Follow up report was faxed on 19-AUG-2020 with the information requested
Aug-19-2020 19:39:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please confirm the abdominal pain was LIFE THREATENING (the definition of grade 4) – “life threatening consequences; urgent intervention indicated, if not update as appropriate. Thanks
Aug-18-2020 18:21:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	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
Jan-28-2021 16:56:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 4: Closed	Response satisfies query
Jan-28-2021 12:44:46	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	The underlying

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		cause was made an issue and the rest of the conditions related were made AE's and were recorded appropriately. Please see added AE#7 ongoing with downgraded severity assessment and previous life threatening severity with an end date
Jan-27-2021 19:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 4: Opened	GPD Clin: Per the severity assessment and answer to query, the event was to be made an SAE. However, SAE is still no. Please confirm.
Sep-23-2020 18:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query

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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-23-2020 14:47:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE Worsening of Abdominal Pain: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Sep-23-2020 14:47:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	New Information
Aug-20-2020 16:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-20-2020 16:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO  Did this serious event requ	New Information

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			<p>ire or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>YES</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	
Aug-19-2020 08:44:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-19-2020 05:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	For AE Increased Abdominal Pain: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.

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Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Increased Abdominal Pain: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	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
Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 10:21:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-22-2020 10:01:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-22-2020 10:01:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study trea tment(s), this event is due t o:  OTHER  <i>If Other, specify:</i>	New Information

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			Ruptured Diverticul m	
Sep-22-2020 08:25:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery Please consider if a more specific reason for increased Abd Pain, now that surgical and pathologic results are available, can be entered to update 'abdominal issue'
Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study trea tment(s), this event is due t o:  OTHER  <i>If Other, specify:</i>  abdominal issue	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

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Date	Location	User	Value	Reason
Aug-18-2020 18:20:52 (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
Sep-29-2020 06:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	event downgraded to non serious in both database.
Sep-23-2020 05:10:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Candidate	SAE RECON: Pending update in SDB data
Sep-22-2020 10:02:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Data is correct. Site will give another safety update as soon as possible
Sep-22-2020 04:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER# 2020319554 ,outcome was updated to RECOVERED/RESOLVED on AE CRF while still RECOVERING/RESOLVING in Safety DB. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Sep-21-2020 16:41:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

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Sep-21-2020 16:41:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> RECOVERED/RE SOLVED	New Information
Sep-21-2020 16:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Worsening of Abdominal Pain: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Aug-28-2020 05:44:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	resolved
Aug-27-2020 12:19:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-27-2020 12:19:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> RECOVERING/RE SOLVING	New Information
Aug-26-2020 03:22:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	SAE RECON:AER# 2020319554 ,outcome was updated to RECOVERING/RESOLVING in SAE form however,reported as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.

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Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERE D/NOT RESOLVE D	Initial Entry
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Aug-18-2020 18:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 18:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	downgraded to non-serious
Aug-19-2020 08:44:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020319554	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Post Operative Ileus	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-20-2020 08:51:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	For downgrading of event in SDB.closing this query since there is Pending query on seriousness field.
Sep-18-2020 17:18:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Site will send SAE follow up update and the original SAE of worsening of Abdominal pain will be the one SAE the others AE's

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Sep-16-2020 08:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 2: Event still serious in SDB. Please confirm if a follow up AEM form was submitted.
Sep-14-2020 04:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candida te	SAE RECON: Pending confirmation if event will be downgraded to non serious in SDB
Sep-11-2020 17:09:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct per hospital records the operation was not on 14AUG2020 this is Postoperative
Sep-09-2020 06:37:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 1: Per latest SAE listing from Safety,onset date was reported as 14Aug2020. Please submit a follow up AEM form to update onset date in Safety database.
Sep-08-2020 16:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-07-2020 04:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020319554
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/18/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

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Date	Location	User	Value	Reason
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Aug/23/2020 00:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

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

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

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

Date	Location	User	Value	Reason
Sep-29-2020 06:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Event seriousness downgraded to Non Serious in SDB data. issue resolved
Sep-23-2020 05:10:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candida te	SAE RECON: Pending update in SDB data
Sep-22-2020 10:03:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Data is correct as entered Site will send another follow up letter as soon as possible
Sep-22-2020 06:04:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON 3: Per latest SAE listing event POST OP ILEUS still serious

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Header Text: c4591001

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Site No: 1083

Subject No: 10831060

Generated By: (b) (4)

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				in SDB.
Sep-20-2020 08:47:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candida te	SAE RECON: Pending submission of follow up AEM form
Sep-18-2020 17:07:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Site will be submitting a SAE follow Up letter
Sep-16-2020 08:21:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON 2: Event still serious in SDB. Please confirm if a follow up AEM form was submitted.
Sep-15-2020 06:37:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candida te	SAE RECON:monitor inactivation in SDB
Sep-14-2020 17:01:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Site will update as non serious and was resolved prior to hospital discharge
Sep-14-2020 04:53:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON 1: Per latest SAE listing POST OP Ileus was still reported as serious. Please confirm if a follow up AEM form was submitted to downgrade event in Safety database.
Sep-11-2020 17:12:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	non-serious is correct site will update and make a new Follow up report
Sep-11-2020 06:37:06 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	pending confirmation on

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1083**Subject No:** 10831060**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

Time (US & Canada)		(b) (4), (b) (6)		SERIOUSNESS
Sep-11-2020 06:34:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 2: Opened	SAE RECON: AER#2020319554 Post-OP Ileus was marked serious in Safety database however this is non-serious in the AE CRF. If this event is serious,update to yes.To downgrade the event in the Safety Database,please submit SAE form.
Sep-07-2020 04:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Post Operative Ileus: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies

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19:01:14 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		query
Sep-15-2020 15:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Worsening of Abdominal pain turned into a small bowel obstruction and needed surgery
Sep-14-2020 20:36:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery: what is the underlying condition?
Sep-11-2020 17:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medically Necessary
Sep-09-2020 04:14:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery:response not satisfactory. please can you confirm why subject had a operation? thanks
Sep-08-2020 16:01:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-08-2020 16:01:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study tre atment(s), this event is du e to:  OTHER  <i>If Other, specify:</i>  Surgical Side Effect	New Information
Sep-07-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Post

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19:39:36 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		Operative Ileus: Question 9 states this AE is in relation to surgical site effect. Please can you confirm the reasoning in the operation subject underwent? Thanks
Sep-04-2020 18:07:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Surgical Site Effect	New Information
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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



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Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 15:23:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 08:32:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	for downgrading to non serious in SDB
Sep-07-2020 04:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020319554	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Sep-18-2020 17:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-18-2020 17:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Sep-18-2020 17:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ruptured diverticulum	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-24-2020 09:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-24-2020 09:50:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-24-2020 09:50:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/14/2020 00:00	Transcription Error
Sep-23-2020 19:39:12 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please update the Start and End

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**Generated By:** (b) (4)

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Time (US & Canada)		(b) (4), (b) (6)		Dates to reflect the changes on the SAE FU report/AE log.
Sep-18-2020 17:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020 00:00	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 09:50:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Aug/24/2020 00:00	New Information
Sep-18-2020 17:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Aug/20/2020 00:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-21-2020 16:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	New Information
Sep-18-2020 17:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

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

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

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Date	Location	User	Value	Reason
Sep-22-2020 11:50:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>YES</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	New Information
Sep-22-2020 04:15:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 16:46:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Ruptured diverticulum: Response to "Is

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				the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-21-2020 16:46:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>YES</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	New Information
Sep-18-2020 17:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> NO</p>	Initial Entry

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Generated By: (b) (4)

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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-18-2020 17:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-22-2020 13:08:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Closed	Response satisfies query
Sep-22-2020 10:05:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treat- ment(s), this event is due t o:  OTHER  If Other, specify:  Infection	New Information
Sep-22-2020 10:05:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Site is entering new AE for Diverticulitis
Sep-21-2020 20:47:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Ruptured diverticulum: Question 9 states this is related to diverticulitis, however, this is not reported as an AE. If this diagnosis was made, please update as

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Header Text: c4591001

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Generated By: (b) (4)

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Subject Initials: ---

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				appropriate. Thanks
Sep-18-2020 17:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Diverticulitis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-08-2020 14:34:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DRUG WITHDRAWN	Transcription Error
Sep-18-2020 17:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-18-2020 17:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-18-2020 17:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

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**Site Name:** (1083) Benchmark Research

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**Generated By:** (b) (4)

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Date	Location	User	Value	Reason
Sep-18-2020 17:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 17:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 04:15:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 2020319554	Initial Entry

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Site No: 1083

Subject No: 10831060

Generated By: (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Sep-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Sep-22-2020 10:22:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-22-2020 10:07:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per PI clinical judgment and assessment of subjects hospital medical records
Sep-22-2020 08:27:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery please confirm if this AE is based on a pathology report? If available, please submit path report high level results as a followup SAE report
Sep-21-2020 16:47:07	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Phlegmon Formation	
Sep-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Phlegmon	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020 00:00	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Aug/20/2020 00:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**7. Is the adverse event serious?****If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Sep-18-2020 17:54:31 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Time (US & Canada)

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-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-22-2020 13:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Closed	Response satisfies query
Sep-22-2020 10:08:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Site is about to enter AE for Diverticulitis
Sep-21-2020 20:46:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Phlegmon: Question 9 states this is related to diverticulitis, however, this is not reported as an AE. If this diagnosis was made, please update as appropriate. Thanks
Sep-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER	Initial Entry

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			<i>If Other, specify:</i>	
			Diverticulitis	

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

Date	Location	User	Value	Reason
Sep-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 17:54:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Sep-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Dec-20-2020 21:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Dec-18-2020 14:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Pre medical records that was the only pathology results
Dec-17-2020 13:31:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	CLINICAL Thank you for SAE update; however the pathological report for resected colon and appendix only states 'negative for malignancy'. Please submit path report for all findings (ie diverticulitis/infection documentation?).

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**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

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Dec-15-2020 12:48:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Query closed; will follow for SAE update with the requested culture test info
Dec-14-2020 17:31:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	SAE Follow Up Letter #12 will be sent this evening after PI signs off.
Dec-10-2020 14:24:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	CLINICAL SAE lab section contains info on 'Culture' taken on unknown date during Hosp. of unknown type (blood/tissue /surgical/other), which was negative. Please update what was cultured, & date, in SAE update
Oct-26-2020 21:02:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for SAE update with colon culture source info
Oct-26-2020 15:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Specimen Right Colon was added to follow up letter
Oct-26-2020 14:44:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-26-2020 14:44:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Openend	Clinical - SAE followup report #10 did not specify what type of culture (blood, stool, urine) was performed; please update the

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				SAE laboratory test section with this information
Oct-26-2020 14:42:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-23-2020 15:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE Follow Up Report #10 was faxed 22OCT2020 PM and reflects the requested changes
Oct-23-2020 15:13:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	SAE Follow Up Report #10 was faxed 22OCT2020 PM and reflects the requested changes
Oct-23-2020 15:12:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Oct-23-2020 03:02:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020319554] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-22-2020 21:22:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Candidate	Clinical COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020319554] to

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				provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-22-2020 21:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Clinical - thank you for this clarified date; please submit the corrected date in a SAE safety update
Oct-22-2020 21:20:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical - please clarify the reported Culture (blood, urine, stool, etc?) during hospitalization, and date it was performed, in a SAE safety update.
Oct-22-2020 18:04:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE Follow Report #10 will reflect the Right Colon Specimen result negative for Malignancy
Oct-22-2020 17:48:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	SC inadvertently recorded 07AUG2020 Instead of the correct date of 17AUG2020 when the MRI was performed per medical records
Oct-22-2020 11:57:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL - SAE for Abd Pain reports an earlier Abd MRI (07 Aug 20), at 1 day after VAX 1. Please submit a SAE safety update clarifying 1) was it preplanned (scheduled before

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				study consent), and 2) what problem was it evaluating
Oct-22-2020 11:53:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical SAE for worsening Abd pain has lab report of 'culture', on unknown date and unknown type [result was neg]. Please submit a SAE safety updated specifying culture type, and date
Sep-24-2020 07:58:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Closed	Response satisfies query
Sep-23-2020 14:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Query is ambiguous
Sep-22-2020 20:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Diverticulitis: Please can you review and confirm if this AE meets any of the symptoms listed in section 8.13 in order to conduct a COVID-19 illness visit? Thanks
Sep-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Diverticulitis	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
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Sep-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020 00:00	Initial Entry
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-26-2021 16:44:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Aug/25/2020 UNK:UNK	closedSAE
Sep-24-2020 07:58:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Closed	Response satisfies query
Sep-23-2020 14:46:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-22-2020 20:03:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Diverticulitis: Please can you confirm if this AE is still ongoing and, if not, please enter a stop date. Thanks
Sep-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-23-2021 14:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	As discussed with the Medical Monitor on 18 Dec 2020, Grade 4 Life threatening = seriousness criteria.

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Jan-08-2021 15:00:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	per protocol AE Life Threatning does not have to be an SAE
Jan-08-2021 12:29:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opene d	Clinical Please clarify guidance required. Diverticulitis ongoing at life threatening Gr 4 over months & not SAE by itself now, has internal contradiction. Please consider the grade now, & stop the Gr 4 event on the day diverticulitis reached lower grade
Dec-31-2020 16:34:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Site awaiting futher guidance
Dec-22-2020 19:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opene d	CLINICAL This Event of diverticulitis is the status of the subject today (ongoing; no end date). Is subject currently affected by a life threatening condition remaining Grade 4 - consider stop grade 4 level, & reenter this event (chronic) at a lower grade
Dec-21-2020 17:33:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	PI and medical monitor had a discussion and PI wil make this an SAE as he does not want to downgrade the Toxicity grade and feels this was a co-finding that was lifethreatening

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				directly related to the underlying condition Ruptured Diverticulum
Dec-17-2020 13:24:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL Diverticulitis AE has Grade 4 severity, which is life-threatening. Please review if ongoing (non-SAE)diverticulitis is currently grade 4.
Dec-09-2020 16:35:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical: CRA will followup
Dec-09-2020 14:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per PI original value is correct
Dec-09-2020 08:03:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: per protocol grade 4 toxicity meets definition for SAE reporting, pls either submit SAE form to sponsor immediately or advise if initial grading was an error and update CRF accordingly. Thanks
Sep-22-2020 10:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	New Information
Sep-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

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*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-26-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 17:48:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Section 28 on SAE Follow Up #10 Report has been updated to show testing as well as negative result
Oct-22-2020 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020319554] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Sep-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Generated By: (b) (4)

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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-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 10:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER <i>If Other, specify:</i>  Infection	New Information
Sep-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER <i>If Other, specify:</i>	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:49:19 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-26-2021 17:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-26-2021 17:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLV ED	New Information
Jan-26-2021 16:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Diverticulitis: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Jan-26-2021 16:54:58 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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Time (US & Canada)				
Jan-26-2021 16:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNKNOWN	life threatening event resolved , however new AE for ongoing Diverticulitis is ongoing -serious not life threatening now
Jan-26-2021 16:44:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Diverticulitis: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOL VING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



Header Text: c4591001

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Generated By: (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Small Bowel Obstruction	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020 00:00	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Aug/20/2020 00:00	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-22-2020 10:22:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-22-2020 10:10:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-22-2020 10:10:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study trea	New Information

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			<p>tment(s), this event is due to:</p> <p>OTHER</p> <p><i>If Other, specify:</i></p> <p>Ruptured Diverticulum</p>	
Sep-22-2020 08:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery please enter the basis for (pre-operative) small bowel obstruction
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p><i>If Other, specify:</i></p>	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>NOT APPLICABLE</p>	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p>YES</p>	Initial Entry

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

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Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 16:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Jan-28-2021 12:59:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-28-2021 12:42:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no past history of this condition
Jan-28-2021 11:29:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls confirm no past hx of diverticulosis/diverticulitis or update MedHx as appropriate. Thanks
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Diverticulitis	Initial Entry

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Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

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Canada)

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-27-2021 11:10:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/26/2020 UNK:UNK	New Information
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  Medical event	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-26-2021 16:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry



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**1. Category:**

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Fatigue	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/7/2021 00:00	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Mar/8/2021 00:00	Initial Entry

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Subject Initials: ---

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Mar-09-2021 13:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Slight Headache	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/7/2021 00:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Mar/8/2021 00:00	Initial Entry

090177e196ae3f94\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, Frozen

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Mar-09-2021 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-09-2021 13:55:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae3f94\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:** 10831060

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:11

Time (US & Canada)

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Mar-09-2021 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f94\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: 10831060

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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**1. Category:**

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Pain-Left	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/7/2021 00:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Mar/8/2021 00:00	Initial Entry

090177e196ae3f94\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, Frozen

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae3f94\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, Frozen

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:11

Time (US & Canada)

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Mar-09-2021 13:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f94\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: 10831060

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1083) Benchmark Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:11

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**1. Category:**

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Muscle Aches	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/7/2021 00:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Mar/8/2021 00:00	Initial Entry

090177e196ae3f94\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, Frozen

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae3f94\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, Frozen

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:11

Time (US & Canada)

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Mar-09-2021 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR - 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

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**1. Category:**

Date	Location	User	Value	Reason
Jan-26-2021 16:56:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Medication Error (Type of Medication Error):**

Date	Location	User	Value	Reason
Jan-26-2021 16:56:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Start Date:**

Date	Location	User	Value	Reason
Jan-26-2021 16:56:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Is the medication error still ongoing?**

Date	Location	User	Value	Reason
Jan-26-2021 16:56:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Jan-26-2021 16:56:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:11

Jan-26-2021 16:56:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**7. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jan-26-2021 16:56:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Did the Medication Error cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Jan-26-2021 16:56:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Was this medication error associated with any adverse events?**

Date	Location	User	Value	Reason
Jan-26-2021 16:56:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**10. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Jan-26-2021 16:56:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - Audit Trail

**Form Version:** 22-Apr-2020 21:03

**Form Status:**

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:11

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Date	Location	User	Value	Reason
Mar-09-2021 13:58:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Mar-09-2021 13:58:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry
Mar-09-2021 13:58:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-26-2021 16:56:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-09-2021 13:58:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry
Mar-09-2021 13:58:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-26-2021 16:56:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Mar-09-2021 13:58:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry
Mar-09-2021 13:58:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:11

Jan-26-2021 16:56:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**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
Mar-09-2021 13:58:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Influenza Vaccine	Initial Entry
Mar-09-2021 13:58:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-26-2021 16:56:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Mar-09-2021 13:58:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/2/2021	Initial Entry
Mar-09-2021 13:58:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-26-2021 16:56:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - 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:** 10831060**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
Jan-26-2021 17:11:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Jan-26-2021 17:11:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Jan-26-2021 17:11:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Jan-26-2021 17:11:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Dose:**

Date	Location	User	Value	Reason
Jan-26-2021 17:11:21 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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: 10831060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Time (US & Canada)				
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6. Dose Unit:

Date	Location	User	Value	Reason
Jan-26-2021 17:11:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Jan-26-2021 17:11:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jan-26-2021 17:11:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jan-26-2021 17:11:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jan-26-2021 17:11:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT - 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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:11

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**1. Category:**

Date	Location	User	Value	Reason
Jan-26-2021 17:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Jan-26-2021 17:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Jan-26-2021 17:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Jan-26-2021 17:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Jan-26-2021 17:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
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090177e196ae3f94\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:** 10831060

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT - 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

Jan-26-2021 17:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - 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

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**1. Transfusion Type:**

Date	Location	User	Value	Reason
Jan-26-2021 17:12:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Date of Transfusion:**

Date	Location	User	Value	Reason
Jan-26-2021 17:12:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f94\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:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:11

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-14-2021 16:29:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/13/2021	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, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:11[Back to Form](#)***1. Select appropriate response - Is participant willing to return for Vaccination 3?***

Date	Location	User	Value	Reason
Mar-10-2021 09:29:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-09-2021 23:55:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	V102 was completed 06MAR2021 and been entered
Mar-03-2021 20:28:45 (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 on the Further Vaccination Confirmation CRF, However Date Written Consent Obtained is missing in Informed Consent - Further Vaccination CRF. Kindly review and update, else clarify.
Jan-14-2021 16:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-14-2021 16:30:03 (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



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION - 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

				is missing in the DISP visit. Please complete this date.
Jan-14-2021 16:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1083

**Subject No:** 10831060

**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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-14-2021 16:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/14/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-14-2021 16:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1083

**Subject No:** 10831060

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - 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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-08-2021 17:46:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/6/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION -  
eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:11

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*I. Consent Was:*

Date	Location	User	Value	Reason
Mar-08-2021 17:46:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Mar/6/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:11

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-08-2021 17:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/6/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-08-2021 17:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-08-2021 17:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**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
Mar-08-2021 17:48:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-08-2021 17:48:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-08-2021 17:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-08-2021 17:48:23 (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.
Mar-08-2021 17:48:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/6/2021	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Mar-08-2021 17:50:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
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5.a

Date	Location	User	Value	Reason
Mar-08-2021 17:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BM2L3V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 17:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM2L3V	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-08-2021 17:50:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BKN1XT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 17:50:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BKN1XT	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-08-2021 17:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: <del>BKN1YC</del>	Transcription Error (DELETED)

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

Mar-08-2021 17:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BKN1YC	Initial Entry
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**5.c Sample ID**

Date	Location	User	Value	Reason
Mar-08-2021 17:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BKN1YC	Transcription Error <b>(DELETED)</b>
Mar-08-2021 17:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BKN1YC	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Mar-08-2021 17:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BM2L4C	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Mar-08-2021 17:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM2L4C	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1083**Site Name:** (1083) Benchmark Research**Subject No:** 10831060**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
Mar-08-2021 17:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-08-2021 17:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-08-2021 17:51:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-08-2021 17:51:34 (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.
Mar-08-2021 17:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/6/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:11

Mar-08-2021 17:51:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BKN1YC	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-08-2021 17:51:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BKN1YC	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1083

Site Name: (1083) Benchmark Research

Subject No: 10831060

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:11

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Mar-08-2021 17:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Mar-08-2021 17:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Mar-08-2021 17:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Mar-08-2021 17:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/6/2021 11:00	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Mar-08-2021 17:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1083

Subject No: 10831060

Generated By: (b) (4)

Form: VACCINATION - 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

Mar-08-2021 17:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Mar-08-2021 17:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Mar-08-2021 17:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Mar-08-2021 17:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Mar-08-2021 17:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Mar-08-2021 17:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:11

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**I. Subject Status**

Date	Location	User	Value	Reason
Mar-11-2021 02:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Email sent to Triad. Awaiting for clarifications.
Mar-09-2021 23:50:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Sorry I do not understand the request
Mar-03-2021 23:36:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	eDiary RQ1: Visit 2 'Symptom Resolved CRF' to be completed to record any 'Symptoms/Reactions' associated with Vaccination 1. eDiary data available for Vaccination 1. Please consider to update Visit 2 'Symptom Resolved CRF' as needed. Else clarify. Thanks
Mar-03-2021 14:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject is continuing in the study for subject safety but per Sponsor guidance in Subject status was told to discontinue subject. Please advise
Mar-02-2021 07:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Vaccination 1 eDiary details are recorded from 06Aug2020 in Trial Max, However

090177e196ae3f94\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1083**Subject No:** 10831060**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

				corresponding 'Symptom Resolved CRF' in Visit 2 is not entered in Inform. Please verify and consider to update appropriate details in Inform as needed. Else, clarify.
Sep-28-2020 14:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	New Information
Sep-24-2020 15:22:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Aug-07-2020 18:05:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMI ZED	Initial Entry
Aug-07-2020 17:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-13-2020 12:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/14/2020	New Information
Sep-28-2020 14:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/15/2020	New Information
Sep-24-2020 15:22:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/15/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1083

**Subject No:** 10831060

**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

Aug-07-2020 18:05:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/6/2020	Initial Entry
Aug-07-2020 17:56:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/6/2020	Initial Entry

090177e196ae3f94\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, Verified

**Site No:** 1083

**Site Name:** (1083) Benchmark Research

**Subject No:** 10831060

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:11

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Sep-22-2020 13:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry