

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/21/2020
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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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11141075]
2.	Birth Date:	(b) (6)/1980
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** DATE OF VISIT

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

**Form Comments**

**Inclusion Criteria Not Met**

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

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

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

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Aug/21/2020
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:** 1114

**Subject No:** 11141075

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergic to Intravenous iodine]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergic to latex]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergic to scopolamine patch]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[myopia]
	Start Date:	UNK/UNK/1993
	Ongoing:	YES

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[seasonal allergies]
	Start Date:	Jun/UNK/2020
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tinea versicolor]
	Start Date:	UNK/UNK/1994
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hyperlipidemia]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[water retention]
	Start Date:	Jan/UNK/2020
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[sleep apnea]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cholelithiasis]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[appendicitis]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[fallopian tube defect]
	Start Date:	UNK/UNK/2007
	Ongoing:	NO End Date: UNK/UNK/2007
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[neck pain]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[anxiety]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[depression]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[neck fusion]
	Start Date:	UNK/UNK/2019
	Ongoing:	NO End Date: UNK/UNK/2019
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hysterectomy]
	Start Date:	UNK/UNK/2007
	Ongoing:	NO End Date: UNK/UNK/2007

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**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cholecystectomy]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[appendectomy]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/21/2020
2.	Weight:	[99.7]
3.	Unit:	kg
4.	Height:	[167.5]
5.	Unit:	cm
6.	Body Mass Index:	[35.5]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

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

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**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** RANDOMIZATION

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/21/2020
2.	Randomization Number:	[61498]
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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5FRB]
5.b	Sample ID	[BP5FRC]
5.c	Sample ID	[BP5FRD]
5.d	Sample ID	[BPR79V]
5.e	Sample ID	[BPR79W]

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**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5FPK]
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** VACCINATION

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[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/21/2020 17:42
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** DATE OF VISIT

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/10/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/10/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/10/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5G0B]
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** VACCINATION

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/10/2020 14:56
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/9/2020
2.	Erroneous Visit	



**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/9/2020
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	[BPVPJG]
5.b	Sample ID	[BPR6TZ]
5.c	Sample ID	[BPR6V0]

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

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

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/20/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

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

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Oct/20/2020
2.	Date of First Symptom Started:	Oct/18/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Dec/14/2020

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	YES
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	YES
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES
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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

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

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

**Symptoms - Other**

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

5.b	Symptoms - Other Text:	[Chest tightness]
-----	------------------------	-------------------

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Nov/17/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** MICROBIOLOGY SPECIMEN

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Nov/17/2020	<a href="#">Comments</a>
2.	Specimen Type:	SWABBED MATERIAL	<a href="#">Comments</a>
3.	Specimen Collection Location:	NASOPHARYNX	<a href="#">Comments</a>
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	<a href="#">Comments</a>
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Comments</a>
6.	Trade Name:	OTHER	<a href="#">Comments</a>
7.	Test Result:	POSITIVE	<a href="#">Comments</a>
8.	Comments/Findings/Details:	[ ]	<a href="#">Comments</a>
9.	Trade Name Other, Specify:	[NALT Unknown]	<a href="#">Comments</a>

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

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

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[Form Comments](#)

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**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 _____ [ ]
----	-----------	--------------------------------

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

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

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/20/2020
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	[BP5G32]
-----	-----------	----------

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** HEALTH CARE UTILIZATION

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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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:	YES Number of Visits or Contacts: [1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** HEALTH CARE UTILIZATION

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

**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:** HOSPITALIZATION DETAILS

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.					<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** HOSPITALIZATION DETAILS

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Hospitalization Details**

1.	Hospitalization Category:	
2.	Hospitalization Term:	
3.	Admission Date:	//
4.	Ongoing?	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Respiratory Treatment**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** ILLNESS DETAILS

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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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: Nov/17/2020
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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** ILLNESS DETAILS - SEVERE

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

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

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Lab Chemistry Details**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

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

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Laboratory Data Hematology**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Date:	Vital Signs Details			Form Instance
1.	Oct/20/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	124	82	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Vital Signs**

1.	Date:	Oct/20/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[124]
	Diastolic:	[82]
	Respiratory Rate in respirations/minute:	[16]
	Heart Rate in beats/minute:	[74]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Date:	Vital Signs Details		Form Instance
1.		<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

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

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Date Time of Assessment	Arterial Blood Gases PaO <sub>2</sub>	FiO <sub>2</sub> (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Concomitant Medications**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled

**Form:** IMAGING

Visit on Oct/20/2020

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Date of Visit**

1.	Date of Visit	Jan/4/2021
2.	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 Jan/04/2021

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

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Jan/4/2021
2.	Date of First Symptom Started:	Dec/28/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Feb/16/2021

**Symptoms**

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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

**Symptoms - Other**

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

**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jan/5/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** MICROBIOLOGY SPECIMEN

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Microbiology Specimen**

1.	Actual Date of Collection:	Jan/5/2021	<a href="#">Comments</a>
2.	Specimen Type:	SWABBED MATERIAL	<a href="#">Comments</a>
3.	Specimen Collection Location:	NASOPHARYNX	<a href="#">Comments</a>
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	<a href="#">Comments</a>
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Comments</a>
6.	Trade Name:	OTHER	<a href="#">Comments</a>
7.	Test Result:	POSITIVE	<a href="#">Comments</a>
8.	Comments/Findings/Details:	[Reactive A]	<a href="#">Comments</a>
9.	Trade Name Other, Specify:	[NALT Unknown]	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[CV26631]
-----	-----------	-----------

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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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:	YES Number of Visits or Contacts: [1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

**Health Care Utilization**

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



**Header Text:** c4591001

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

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Jan/5/2021	NO Discharge Date : Jan/13/2021	<a href="#">Repeating Pages</a>

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** HOSPITALIZATION DETAILS

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Jan/5/2021
4.	Ongoing?	NO Discharge Date: Jan/13/2021

**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	1	YES	HIGH FLOW OXYGEN THERAPY	HIGH FLOW OXYGEN THERAPY	Jan/5/2021	<a href="#">Repeating Pages</a>

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Respiratory Treatment**

1.	What is the treatment Identifier?	[1]	<a href="#">Comments</a>
2.	Concomitant Non-drug Treatment Pre-specified:	YES	<a href="#">Comments</a>
3.	Treatment:	HIGH FLOW OXYGEN THERAPY	<a href="#">Comments</a>
4.	Treatment:	[HIGH FLOW OXYGEN THERAPY]	<a href="#">Comments</a>
5.	Start Date:	Jan/5/2021	<a href="#">Comments</a>
6.	Ongoing?	NO End Date: Jan/11/2021	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** ILLNESS DETAILS

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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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 pneumonia]  Date of Diagnosis: Jan/7/2021
3.	Toxicity Grade:	1

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**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** ILLNESS DETAILS - SEVERE

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Illness Details**

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

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Header Text: c4591001

Visit: POT\_COVID\_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	CLINICAL CHEMISTRY	Newton Medical Center Laboratory 600 Medical Center Dr. Newton Kansas 67114	Jan/6/2021	BLOOD	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					329	C Reactive Protein_PX329	54.8	
					30	Alanine Aminotransferase_PX30	59	
					28	Aspartate Aminotransferase_PX28	64	
					35	Alkaline Phosphatase_PX35	95	
					21	Bilirubin_PX21	0.4	
					47	Blood Urea Nitrogen_PX47	16	
					48	Creatinine_PX48	.8	

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Newton Medical Center Laboratory 600 Medical Center Dr. Newton Kansas 67114]
3.	Collection Date:	Jan/6/2021
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[54.8]
	Not Done:	
	LNMT	Low [0] High [9] Unit mg/L
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[59]
	Not Done:	
	LNMT	Low [1] High [35] Unit U/L

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[64]
	Not Done:	
	LNMT	Low [14] High [36] Unit U/L

5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[95]
	Not Done:	
	LNMT	Low [38] High [126] Unit U/L

5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[0.4]
	Not Done:	
	LNMT	Low [.2] High [1.3] Unit mg/dL

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

5 f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[16]
	Not Done:	
	LNMT	Low [7] High [17] Unit mg/dL

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[.8]
	Not Done:	
	LNMT	Low [.7] High [1.2] Unit mg/dL

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Header Text: c4591001

Visit: POT\_COVID\_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result	Form Instance																																	
1.	HEMATOLOGY	Newton Medical Center Laboratory 600 Medical Center Dr. Newton Kansas 67114	Jan/6/2021	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Hemoglobin_PX1</td> <td>13.9</td> </tr> <tr> <td>2</td> <td>Hematocrit_PX2</td> <td>42.4</td> </tr> <tr> <td>3</td> <td>Erythrocytes_PX3</td> <td>5.07</td> </tr> <tr> <td>5</td> <td>Platelets_PX5</td> <td>239</td> </tr> <tr> <td>7</td> <td>Leukocytes_PX7</td> <td>[ ]</td> </tr> <tr> <td>608</td> <td>Neutrophils_PX608</td> <td>4.5</td> </tr> <tr> <td>609</td> <td>Eosinophils_PX609</td> <td>0</td> </tr> <tr> <td>612</td> <td>Monocytes_PX612</td> <td>6</td> </tr> <tr> <td>610</td> <td>Basophils_PX610</td> <td>0</td> </tr> <tr> <td>611</td> <td>Lymphocytes_PX611</td> <td>0.8</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	1	Hemoglobin_PX1	13.9	2	Hematocrit_PX2	42.4	3	Erythrocytes_PX3	5.07	5	Platelets_PX5	239	7	Leukocytes_PX7	[ ]	608	Neutrophils_PX608	4.5	609	Eosinophils_PX609	0	612	Monocytes_PX612	6	610	Basophils_PX610	0	611	Lymphocytes_PX611	0.8	<a href="#">Repeating Pages</a>
Sponsor-Defined Identifier	Test:	Result:																																					
1	Hemoglobin_PX1	13.9																																					
2	Hematocrit_PX2	42.4																																					
3	Erythrocytes_PX3	5.07																																					
5	Platelets_PX5	239																																					
7	Leukocytes_PX7	[ ]																																					
608	Neutrophils_PX608	4.5																																					
609	Eosinophils_PX609	0																																					
612	Monocytes_PX612	6																																					
610	Basophils_PX610	0																																					
611	Lymphocytes_PX611	0.8																																					

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Newton Medical Center Laboratory 600 Medical Center Dr. Newton Kansas 67114]
3.	Collection Date:	Jan/6/2021
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[13.9]
	Not Done:	
	LNMT	Low [12] High [16] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[42.4]
	Not Done:	
	LNMT	Low [36] High [46] Unit %

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

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**Generated Time (GMT):** 29-Mar-2021 10:58

5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[5.07]
	Not Done:	
	LNMT	Low [4] High [5.2] Unit /uL

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[239]
	Not Done:	
	LNMT	Low [130] High [400] Unit 10^6/cu mm

5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

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**Subject Initials:** ---

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

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5 f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[4.5]
	Not Done:	
	LNMT	Low [1.8] High [7.7] Unit 10^6/cu mm

5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0]
	Not Done:	
	LNMT	Low [0] High [4] Unit %

5 h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[6]
	Not Done:	
	LNMT	Low [0] High [9] Unit %

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0]
	Not Done:	
	LNMT	Low [0] High [2] Unit %

5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[0.8]
	Not Done:	
	LNMT	Low [1] High [4.8] Unit 10^6/cu mm

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Date:	Vital Signs Details			Form Instance
1.	Jan/6/2021	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	118	79	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Vital Signs**

1.	Date:	Jan/6/2021
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[118]
	Diastolic:	[79]
	Respiratory Rate in respirations/minute:	[19]
	Heart Rate in beats/minute:	[93]

**Header Text:** c4591001

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

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Date:	Vital Signs Details		Form Instance
1.	Jan/5/2021	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	86.0	

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Vital Signs**

1.	Date:	Jan/5/2021
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[86.0]

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	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>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	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 Jan/04/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Feb/5/2021	CHEST	X-RAY	INDETERMINATE	<a href="#">Repeating Pages</a>
2.	Feb/7/2021	CHEST	CT SCAN	ABNORMAL <i>If abnormal, specify findings:</i>  Pulmonary findings consistent with COVID-19 pneumonia of moderate severity. Developing bacterial superinfection in the lower lobes cannot be excluded.	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

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

**Form:** IMAGING

Visit on Jan/04/2021

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Imaging**

1.	Date of Assessment:	Feb/5/2021	<a href="#">Comments</a>
2.	Location of Assessment:	CHEST	<a href="#">Comments</a>
3.	Type of Imaging Exam:	X-RAY	<a href="#">Comments</a>
4.	Assessment:	INDETERMINATE	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** IMAGING

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Imaging**

1.	Date of Assessment:	Feb/7/2021
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Pulmonary findings consistent with COVID-19 pneumonia of moderate severity. Developing bacterial superinfection in the lower lobes cannot be excluded.]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Nov/23/2020

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

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Date of Visit**

1.	Date of Visit	Nov/23/2020
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 Nov/23/2020

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/23/2020
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	[BPR6ZW]
5.b	Sample ID	[BPR6ZX]
5.c	Sample ID	[BPVPLZ]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Date of Visit**

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

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_B1
----	-------------------------	----------

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 -  
Unscheduled Visit on Feb/05/2021

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/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	[BM3CKB]
5.b	Sample ID	[BM3CKC]
5.c	Sample ID	[BPVPRX]

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**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/9/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB  
Unscheduled Visit

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB  
Unscheduled Visit

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED	ADVERSE EVENT	1	Covid-19 Illness A	Oct/18/2020 09:00	YES	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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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)	[Covid-19 illness A]
4.	Start Date Time:	Oct/18/2020 09:00
5.	Is the adverse event still ongoing?	YES
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:** 1114

**Subject No:** 11141075

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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

9.	Is this event related to study treatment:	<del>NOT RELATED</del> If Not Related to study treatment(s), this event is due to: <del>OTHER</del> If Other, specify: [Viral Infection]
10.	Latest Action Taken with Study Treatment:	<del>NOT APPLICABLE</del>
11.	Was a Concomitant Medication given?	<del>YES</del>
12.	Was a Non-Drug Treatment given?	<del>NO</del>
13.	What was the outcome of this adverse event?:	<del>NOT RECOVERED/NOT RESOLVED</del>
14.	Did the adverse event cause the subject to be discontinued from the study?	<del>NO</del>
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Medication Error**

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

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**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Concomitant Medications**

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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1. DELETED						<a href="#">Repeating Pages</a>
2. DELETED						<a href="#">Repeating Pages</a>
3. DELETED						<a href="#">Repeating Pages</a>
4. DELETED						<a href="#">Repeating Pages</a>
5. DELETED						<a href="#">Repeating Pages</a>
6. DELETED						<a href="#">Repeating Pages</a>
7. DELETED						<a href="#">Repeating Pages</a>
8. DELETED						<a href="#">Repeating Pages</a>
9. DELETED						<a href="#">Repeating Pages</a>
10. DELETED						<a href="#">Repeating Pages</a>
11. DELETED						<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Concomitant Medications**

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]	
2.	Category:		<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:		
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]	
5.	Dose:	[ ]	
6.	Dose Unit:		
7.	Dose Frequency:		
8.	Route:		
9.	Start Date:	//	
10.	Ongoing?		

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
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5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
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**Concomitant Medications**

1.	What is the medication identifier?	[ ]	
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**Form Version:** 22-Apr-2020 21:03

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**Concomitant Medications**

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**Concomitant Medications**

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

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**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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**Site Name:** (1114) Alliance for Multispecialty Research Inc

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**Site Name:** (1114) Alliance for Multispecialty Research Inc

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

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**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site Name:** (1114) Alliance for Multispecialty Research Inc

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**Site Name:** (1114) Alliance for Multispecialty Research Inc

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]	
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5.	Dose:	[ ]	
6.	Dose Unit:		
7.	Dose Frequency:		
8.	Route:		
9.	Start Date:	//	
10.	Ongoing?		

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**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled    **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02    **Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled    **Form:** VACCINATION

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**Vaccination**

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled    **Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57    **Form Status:** Not Started

**Site No:** 1114    **Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 10:58

**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:** 1114    **Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 10:58

**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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Date of Visit**

1.	Date of Visit	Jan/28/2021
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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Treatment Unblinded**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

**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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**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:** 1114

**Subject No:** 11141075

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Not Started

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

**Informed Consent - Further Vaccination**

1.	Consent Was:	
----	--------------	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

**Form Status:** Not Started

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**Disposition - Screening for Further Vaccination**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/9/2020

**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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

[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:** 1114

**Subject No:** 11141075

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

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**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

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**Form Version:** 21-Aug-2020 02:49

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**Subject No:** 11141075

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

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**Subject Initials:** ---

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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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Visit on Oct/20/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

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Item	Date	User	Comment
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Item	Date	User	Comment
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3	Oct-26-2020 08:23:32 (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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**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**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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**Subject No:** 11141075

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

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SELF - 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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Visit on Jan/04/2021

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

**Form Status:** Data Complete, Frozen

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**Subject No:** 11141075

**Subject Initials:** ---

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Item	Date	User	Comment
Form	Feb-08-2021 15:39:48 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Jan-06-2021 08:23:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done _____ Not Done



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**Subject Initials:** ---

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

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Item	Date	User	Comment
8	Feb-08-2021 15:39:48 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
8	Jan-06-2021 08:23:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done <hr/> Not Done



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Visit on Jan/04/2021

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete, Frozen

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**Subject No:** 11141075

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 10:58

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9	Feb-08-2021 15:39:48 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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Visit on Jan/04/2021

**Form:** RESPIRATORY TREATMENT - Comments

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

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Form	Feb-08-2021 09:48:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable _____ Not Applicable
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6	Feb-08-2021 09:48:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable _____ Not Applicable
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Visit on Jan/04/2021

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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Item	Date	User	Comment
Form	Feb-18-2021 08:19:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done Not Done
Form	Feb-16-2021 08:23:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Feb-11-2021 14:28:48 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable Not Applicable

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Item	Date	User	Comment
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1	Feb-16-2021 08:23:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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Item	Date	User	Comment
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2	Feb-16-2021 08:23:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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Item	Date	User	Comment
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3	Feb-16-2021 08:23:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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Item	Date	User	Comment
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4	Feb-16-2021 08:23:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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**Form:** OXYGENATION PARAMETERS - Comments

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**Subject No:** 11141075

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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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1	Feb-08-2021 09:52:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable <hr/> Not Applicable

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2	Feb-08-2021 09:52:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable <hr/> Not Applicable

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Item	Date	User	Comment
4	Feb-09-2021 14:23:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Feb-08-2021 09:52:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Item	Date	User	Comment
Form	Feb-26-2021 16:20:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Medication given during COVID treatment and recorded

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED -  
Comments

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Item	Date	User	Comment
Form	Feb-26-2021 16:21:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Medication given during COVID treatment and recorded

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Item	Date	User	Comment
2	Mar-04-2021 08:24:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Feb-11-2021 14:38:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
			Not Applicable



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Item	Date	User	Comment
2	Mar-04-2021 08:37:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Feb-11-2021 14:41:51 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
			Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Item	Date	User	Comment
2	Mar-04-2021 08:39:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Feb-11-2021 15:10:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
			Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Item	Date	User	Comment
2	Mar-04-2021 08:44:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Feb-11-2021 15:12:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
			Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Item	Date	User	Comment
2	Mar-04-2021 08:46:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Feb-11-2021 15:13:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
			Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Item	Date	User	Comment
2	Mar-04-2021 08:53:55 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Feb-11-2021 15:35:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
			Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Item	Date	User	Comment
2	Mar-04-2021 08:57:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Feb-11-2021 15:36:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
			Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Item	Date	User	Comment
2	Mar-04-2021 09:00:20 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Feb-11-2021 17:19:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
			Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Item	Date	User	Comment
2	Mar-04-2021 09:02:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Feb-11-2021 17:20:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
			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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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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	Jan-28-2021 10:23:40 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Richard Glover	Approved	Jan-25-2021 11:44:57 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, RichardGlover, 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	Dec-04-2020 14:45:27 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Richard Glover	Approved	Dec-02-2020 13:41:50 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-24-2020 08:27:02 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Richard Glover	Approved	Oct-26-2020 17:21:03 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Oct-26-2020 08:21:40 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Richard Glover	Approved	Oct-23-2020 10:08:49 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**Affidavit:**

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

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

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

(b) (6)	N/A	Oct-21-2020 16:12:45 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Richard Glover	Approved	Oct-21-2020 14:37:02 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, RichardGlover, 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.

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-22-2020 12:18:20 (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-22-2020 12:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-22-2020 12:18:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/21/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-22-2020 12:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11141075	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-22-2020 12:17:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1980	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-22-2020 12:18:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-22-2020 12:18:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:18:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-22-2020 12:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/21/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Aug-22-2020 12:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/21/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-22-2020 12:20:04 (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-22-2020 12:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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*I.a*

Date	Location	User	Value	Reason
Aug-22-2020 12:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Nu 1 mber: <b>Medical History Term:</b> allergic to Intravenous iodine <b>Start Date:</b> UNK/UNK/2006 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-22-2020 12:22:31 (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-22-2020 12:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> allergic to Intravenous iodine	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Aug-22-2020 12:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2006	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

Aug-22-2020 12:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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*1.b*

Date	Location	User	Value	Reason
Aug-22-2020 12:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Numbe</b> 2 <b>r:</b> <b>Medical History</b> allergic to la <b>Term:</b> tex <b>Start Date:</b> UNK/UNK/ 2000 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Aug-22-2020 12:22:54 (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-22-2020 12:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> allergic to latex	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 12:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2000	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 12:22:54 (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-22-2020 12:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> allergic to scopolamine patch <b>Start Date:</b> UNK/UNK/2019 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-22-2020 12:23:22 (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-22-2020 12:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> allergic to scopolamine patch	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 12:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 12:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-22-2020 12:23:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numbe 4 r: Medical History myopia Term: Start Date: UNK/UNK/ 1993 Ongoing: YES	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-22-2020 12:23:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:23:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> myopia	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 12:23:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1993	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 12:23:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Aug-22-2020 12:24:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numbe 5 r: <b>Medical History</b> seasonal alle <b>Term:</b> rgies <b>Start Date:</b> Jun/UNK/20 20 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

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Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Aug-22-2020 12:24:02 (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-22-2020 12:24:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> seasonal allergies	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Aug-22-2020 12:24:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/UNK/2020	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Aug-22-2020 12:24:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Aug-22-2020 12:24:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numbe 6 r: <b>Medical History</b> tinea versico <b>Term:</b> lor <b>Start Date:</b> UNK/UNK/ 1994 <b>Ongoing:</b> YES	Initial Entry

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Header Text: c4591001

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Subject No: 11141075

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*1.f Line/MH Number:*

Date	Location	User	Value	Reason
Aug-22-2020 12:24:24 (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-22-2020 12:24:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> tinea versicolor	Initial Entry

*1.f Start Date:*

Date	Location	User	Value	Reason
Aug-22-2020 12:24:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1994	Initial Entry

*1.f Ongoing:*

Date	Location	User	Value	Reason
Aug-22-2020 12:24:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*1.g*

Date	Location	User	Value	Reason
Aug-22-2020 12:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numbe 7 r: Medical History hyperlipide Term: mia Start Date: UNK/UNK/ 2019 Ongoing: YES	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

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Subject No: 11141075

Generated By: (b) (4)

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

***1.g Line/MH Number:***

Date	Location	User	Value	Reason
Aug-22-2020 12:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hyperlipidemia	Initial Entry

***1.g Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 12:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

***1.g Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 12:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.h***

Date	Location	User	Value	Reason
Aug-22-2020 12:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numbe 8 r: <b>Medical History Term:</b> water retent ion <b>Start Date:</b> Jan/UNK/2 020 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



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Subject Initials: ---

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***1.h Line/MH Number:***

Date	Location	User	Value	Reason
Aug-22-2020 12:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> water retention	Initial Entry

***1.h Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 12:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/UNK/2020	Initial Entry

***1.h Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 12:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.i***

Date	Location	User	Value	Reason
Aug-22-2020 12:27:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numbe 9 r: Medical History sleep apnea Term: Start Date: UNK/UNK/ 2019 Ongoing: YES	Initial Entry

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject Initials: ---

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***1.i Line/MH Number:***

Date	Location	User	Value	Reason
Aug-22-2020 12:27:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:27:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> sleep apnea	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 12:27:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 12:27:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.j***

Date	Location	User	Value	Reason
Aug-22-2020 12:27:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Num 10 <b>ber:</b> Medical Histor cholelithiasis <b>y Term:</b> <b>Start Date:</b> UNK/UNK/2017	Initial Entry

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Subject No: 11141075

Generated By: (b) (4)

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Subject Initials: ---

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			<b>Ongoing:</b> NO End Date:  UNK/UNK /2017	
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**1.j Line/MH Number:**

Date	Location	User	Value	Reason
Aug-22-2020 12:27:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:27:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cholelithiasis	Initial Entry

**1.j Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 12:27:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**1.j Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 12:27:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2017	Initial Entry

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**Header Text:** c4591001

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**Site No:** 1114

**Subject No:** 11141075

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

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

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<i>I.k</i>				
Date	Location	User	Value	Reason
Aug-22-2020 12:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 11 <b>ber:</b> <b>Medical Histor</b> appendicitis <b>y Term:</b> <b>Start Date:</b> UNK/UNK/20 17 <b>Ongoing:</b> NO End Date: UNK/UNK /2017	Initial Entry

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**1.k Line/MH Number:**

Date	Location	User	Value	Reason
Aug-22-2020 12:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> appendicitis	Initial Entry

**1.k Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 12:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**1.k Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 12:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2017	Initial Entry

**1.l**

Date	Location	User	Value	Reason
Aug-22-2020 12:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Num 12 <b>ber:</b> <b>Medical Histor</b> fallopian tube <b>y Term:</b> defect	Initial Entry

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			<b>Start Date:</b> UNK/UNK/2007 <b>Ongoing:</b> NO End Date: UNK/UNK/2007
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**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Aug-22-2020 12:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

**1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-22-2020 12:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> fallopian tube defect	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 12:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2007	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 12:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2007	Initial Entry

**1.m**

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Date	Location	User	Value	Reason
Aug-24-2020 11:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 13 <b>Medical History Term:</b> neck pain <b>Start Date:</b> UNK/UNK/2019 <b>Ongoing:</b> YES	Changed Information
Aug-22-2020 12:29:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 13 <b>Medical History Term:</b> neck pain <b>Start Date:</b> UNK/UNK/2019 <b>Ongoing:</b> NO End Date: UNK/UNK/2019	Initial Entry

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***1.m Line/MH Number:***

Date	Location	User	Value	Reason
Aug-22-2020 12:29:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:29:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> neck pain	Initial Entry

***1.m Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 12:29:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

***1.m Ongoing:***

Date	Location	User	Value	Reason
Aug-24-2020 11:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Changed Information
Aug-22-2020 12:29:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2019	Initial Entry

***1.n***

Date	Location	User	Value	Reason
Aug-22-2020 12:29:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Numbr:</b> 14	Initial Entry

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			<b>Medical History</b> anxiety <b>Term:</b> <b>Start Date:</b> UNK/UNK/ 2000 <b>Ongoing:</b> YES	
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***1.n Line/MH Number:***

Date	Location	User	Value	Reason
Aug-22-2020 12:29:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 14	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:29:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> anxiety	Initial Entry

***1.n Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 12:29:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2000	Initial Entry

***1.n Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 12:29:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.o***

Date	Location	User	Value	Reason
Aug-22-2020 12:30:03 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 15	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Time (US & Canada)			er: Medical History depression Term: Start Date: UNK/UNK/ 2019 Ongoing: YES
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***1.o Line/MH Number:***

Date	Location	User	Value	Reason
Aug-22-2020 12:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 15	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> depression	Initial Entry

***1.o Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 12:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

***1.o Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 12:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.p***

Date	Location	User	Value	Reason
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

<p>Aug-22-2020 12:30:34 (UTC-06:00) Central Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p><b>Data Entry:</b>  <b>Line/MH Number:</b> 16  <b>Medical History Term:</b> neck fusion  <b>Start Date:</b> UNK/UNK/2019  <b>Ongoing:</b> NO  <b>End Date:</b> UNK/UNK/2019</p>	<p>Initial Entry</p>
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

***1.p Line/MH Number:***

Date	Location	User	Value	Reason
Aug-22-2020 12:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 16	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> neck fusion	Initial Entry

***1.p Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 12:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

***1.p Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 12:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2019	Initial Entry

***1.q***

Date	Location	User	Value	Reason
Aug-22-2020 12:31:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 17 <b>ber:</b> <b>Medical Histor</b> hysterectomy <b>y Term:</b>	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

			<b>Start Date:</b> UNK/UNK/2007 <b>Ongoing:</b> NO End Date: UNK/UNK/2007
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**1.q Line/MH Number:**

Date	Location	User	Value	Reason
Aug-22-2020 12:31:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 17	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:31:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hysterectomy	Initial Entry

**1.q Start Date:**

Date	Location	User	Value	Reason
Aug-22-2020 12:31:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2007	Initial Entry

**1.q Ongoing:**

Date	Location	User	Value	Reason
Aug-22-2020 12:31:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2007	Initial Entry

**1.r**

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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Aug-22-2020 12:31:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 18 <b>ber:</b> <b>Medical Histor</b> cholecystecto <b>y Term:</b> my <b>Start Date:</b> UNK/UNK/20 17 <b>Ongoing:</b> NO End Date:  UNK/UNK /2017	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Aug-22-2020 12:31:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 18	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:31:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cholecystectomy	Initial Entry

***I.r Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 12:31:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

***I.r Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 12:31:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2017	Initial Entry

***I.s***

Date	Location	User	Value	Reason
Aug-22-2020 12:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Num 19 ber: Medical Histor appendectomy y Term:	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

			<b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> NO End Date: UNK/UNK/2017
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***1.s Line/MH Number:***

Date	Location	User	Value	Reason
Aug-22-2020 12:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 19	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> appendectomy	Initial Entry

***1.s Start Date:***

Date	Location	User	Value	Reason
Aug-22-2020 12:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

***1.s Ongoing:***

Date	Location	User	Value	Reason
Aug-22-2020 12:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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**1. Date:**

Date	Location	User	Value	Reason
Aug-22-2020 12:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/21/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-22-2020 12:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 99.7	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-22-2020 12:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-22-2020 12:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 167.5	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-22-2020 12:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Aug-22-2020 12:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35.5	Initial Entry
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7.a

Date	Location	User	Value	Reason
Aug-22-2020 12:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifie 1 r:: Temperature: 36.7 Temperature U C nit: Temperature Lo ORAL CA cation:: VITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-22-2020 12:32:41 (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-22-2020 12:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-22-2020 12:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

Aug-22-2020 12:32:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-22-2020 12:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-22-2020 12:33:50 (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
Aug-22-2020 12:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Aug-22-2020 12:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-22-2020 12:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Aug-22-2020 12:33:50 (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	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-22-2020 12:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-22-2020 12:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-22-2020 12:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-22-2020 12:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-22-2020 12:34:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/21/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-22-2020 12:34:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 61498	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-22-2020 12:36:33 (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-22-2020 12:36:33 (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
Aug-22-2020 12:36:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-22-2020 12:36:33 (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-22-2020 12:36:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (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: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Aug-22-2020 12:36:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP5FRB	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 12:36:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5FRB	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-22-2020 12:36:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP5FRC	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 12:36:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5FRC	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-22-2020 12:37:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP5FRD	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 12:37:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5FRD	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (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: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d

Date	Location	User	Value	Reason
Aug-22-2020 12:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPR79V</b>	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 12:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPR79V	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-22-2020 12:38:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPR79W</b>	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 12:38:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPR79W	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (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:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-22-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-22-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-22-2020 12:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-22-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-22-2020 12:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Aug-22-2020 12:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP5FPK	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-22-2020 12:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5FPK	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Aug-22-2020 12:40:57 (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
Aug-22-2020 12:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-22-2020 12:40:57 (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
Aug-22-2020 12:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/21/2020 17:42	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-22-2020 12:40:57 (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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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

Aug-22-2020 12:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Aug-22-2020 12:40:57 (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-22-2020 12:40:57 (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-22-2020 12:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-22-2020 13:03:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E- DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-10-2020 16:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/10/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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**1. Date:**

Date	Location	User	Value	Reason
Sep-10-2020 16:35:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/10/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-10-2020 16:35:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> Temperature: 36.7 Temperature Unit: ORAL CAVITY Temperature Location: ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-10-2020 16:35:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-10-2020 16:35:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.7	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

Sep-10-2020 16:35:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry
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**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-10-2020 16:35:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 21-Aug-2020 02:49

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-10-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-10-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-10-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/10/2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-10-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Sep-10-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> 113 : <b>Test::</b> Choriogonadotropin Beta_PX13 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-10-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-10-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX13	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Sep-10-2020 16:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-10-2020 17:03:34 (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
Sep-10-2020 17:03:34 (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
Sep-10-2020 17:03:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 17:03:34 (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.
Sep-10-2020 17:03:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/10/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Sep-10-2020 17:03:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP5G0B	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-10-2020 17:03:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5G0B	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Sep-10-2020 16:36:05 (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
Sep-10-2020 16:36:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-10-2020 16:36:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-10-2020 16:36:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/10/2020 14:56	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-10-2020 16:36:05 (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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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

Sep-10-2020 16:36:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Sep-10-2020 16:36:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-10-2020 16:36:05 (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
Sep-10-2020 16:36:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-12-2020 09:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 10:48:27 (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-14-2020 10:48:27 (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-14-2020 10:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/9/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-14-2020 10:48:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPVPJG	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 10:48:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVPJG	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**5.b**

Date	Location	User	Value	Reason
Oct-14-2020 10:48:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPR6TZ	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 10:48:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPR6TZ	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-14-2020 10:49:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPR6V0	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-14-2020 10:49:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPR6V0	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**I. Date of Visit**

Date	Location	User	Value	Reason
Feb-26-2021 15:41:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Puig (b) (4)	Query 6: Closed	hospitalization form not required
Feb-26-2021 06:26:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	DM: Kindly consider to update missing HOSPITALIZATION DETAILS form at COVID ILL visit or else clarify. Thank you.
Feb-15-2021 16:57:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	follow up with CRA
Feb-15-2021 16:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Open ed	Per the SOD form the Last Symptom Resolved on 14DEC2020. Please confirm with the CRA and source documents. Please enter HOSP record details on the forms within this visit.
Feb-15-2021 08:32:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	symptoms have not resolved yet
Feb-15-2021 06:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Open ed	DM2: Please confirm if the HOSP details can now be obtained as Symptoms

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1114**Subject No:** 11141075**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail  
History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

				resolved 14Dec20. Please reach out to the subject to retrieve all possible details.
Feb-08-2021 17:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Candid ate	Re-issue as open if details not updated by 11Feb21
Feb-08-2021 10:17:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Waiting for ROR to come back to fill out all needed forms
Feb-08-2021 06:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Opene d	DM1: Please confirm if the HOSP details can now be obtained as Symptoms resolved 14Dec20. Please reach out to the subject to retrieve all possible details.
Feb-03-2021 13:14:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued:Candid ate	Re-issue as open by 08Feb21 if data is not updated on HOSP details form
Feb-03-2021 09:34:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	We have sent a ROR will update once records are received
Feb-02-2021 15:54:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Please confirm if the HOSP details can now be obtained as Symptoms resolved 14Dec20. Please reach out to the subject to retrieve all possible details.
Feb-02-2021 15:52:51	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Reword and issue in open state

<b>Header Text:</b> c4591001				
<b>Visit:</b> POT_COVID_ILL 1 - Unscheduled Visit on Oct/20/2020		<b>Form:</b> DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History		
<b>Form Version:</b> 22-Apr-2020 21:03		<b>Form Status:</b> Data Complete, Frozen, Verified		
<b>Site No:</b> 1114		<b>Site Name:</b> (1114) Alliance for Multispecialty Research Inc		
<b>Subject No:</b> 11141075		<b>Subject Initials:</b> ---		
<b>Generated By:</b> (b) (4)		<b>Generated Time (GMT):</b> 29-Mar-2021 10:58		
(UTC-06:00) Central Time (US & Canada)				
Feb-02-2021 15:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	Subject still hospitalized will gather information when subject gets released
Jan-25-2021 15:13:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Candidate	Subject still hospitalized will gather information when subject gets released
Jan-25-2021 08:32:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Subject still hospitalized will gather information when subject gets released
Jan-22-2021 02:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	DM: Kindly consider to update missing HOSPITALIZATION DETAILS form or else clarify. Thank you.
Oct-26-2020 13:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-26-2020 08:28:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Oct-26-2020 05:17:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Health Care Utilization, Microbiology Specimen, Illness Details and Nasal Swab self form' at

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1114**Subject No:** 11141075**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail  
History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

				this visit. Thank you.
Oct-21-2020 10:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 10:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-21-2020 10:38:32 (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.
Oct-21-2020 10:38:32 (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.
Oct-21-2020 10:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 10:38:32 (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 Oct/20/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-21-2020 10:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Oct-21-2020 10:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/18/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Jan-08-2021 00:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-07-2021 08:25:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-07-2021 08:25:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Dec/14/2020	New Information
Jan-07-2021 00:32:43 (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

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

				the date of last symptom resolved as appropriate. If not, please move details from next visit into this visit. Thank you.
Oct-21-2020 10:40:14 (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
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> YES	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (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
Oct-21-2020 10:39:36 (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
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCRE : ASSED COUGH	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/20/2020

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**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

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**Subject Initials:** ---

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

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			Symptom YES Present:	
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**4.b Symptoms:**

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Nov-24-2020 13:57:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	Changed Information
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**4.c Symptoms:**

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHOR TNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Nov-24-2020 13:57:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Changed Information
Oct-21-2020 10:39:36 (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
Nov-24-2020 13:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Changed Information
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> YES	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/20/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

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**4.d Symptoms:**

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (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
Nov-24-2020 13:57:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Changed Information
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (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> YES	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
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4.e Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUS CLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom NEW LOSS OF T s: ASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR S MELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Generated By:** (b) (4)

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Date	Location	User	Value	Reason
Nov-24-2020 13:58:45 (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	Changed Information
Nov-24-2020 13:57:56 (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> NO	Changed Information
Oct-21-2020 10:39:36 (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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/20/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**4.g Symptoms:**

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (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
Nov-24-2020 13:58:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Changed Information
Nov-24-2020 13:57:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Changed Information
Oct-21-2020 10:39:36 (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
Oct-21-2020 10:39:36 (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	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**4.h Symptoms:**

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (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
Oct-21-2020 10:39:36 (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
Oct-21-2020 10:39:36 (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

**4.i Symptoms:**

Date	Location	User	Value	Reason
Oct-21-2020 10:39:36 (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
Oct-21-2020 10:39:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/20/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Nov-24-2020 13:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other Headache	Changed Information (DELETED)
Oct-21-2020 16:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other Headache	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-24-2020 13:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Headache	Changed Information (DELETED)
Oct-21-2020 16:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Headache	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-24-2020 13:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other: Chest tightness	Changed Information (DELETED)
Oct-21-2020 16:17:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other: Chest tightness	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Not Complete

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

**5.b Symptoms - Other Text:**

Date	Location	User	Value	Reason
Nov-24-2020 13:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <del>Chest tightness</del>	Changed Information <b>(DELETED)</b>
Oct-21-2020 16:17:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Chest tightness	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Nov-24-2020 14:04:52 (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 Oct/20/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Nov-24-2020 14:04:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/17/2020	Initial Entry
Nov-24-2020 14:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-26-2020 08:23:32 (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-08-2020 04:54:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Queried at item# 6.
Dec-07-2020 13:32:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Records received, updated
Dec-07-2020 00:55:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: The response for Data item# 6 is missing. Kindly review and update.
Dec-04-2020 14:45:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-04-2020 14:45:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Transcription Error
Nov-25-2020 22:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Per response, please answer the query

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

				once the data is available and updated in CRF. Thank you
Nov-25-2020 08:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Awaiting records be released
Nov-25-2020 00:29:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for Data item#2,3 and 6 are missing. Kindly review and update.
Nov-24-2020 14:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-26-2020 08:23:32 (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-04-2020 14:46:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry
Nov-24-2020 14:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-26-2020 08:23:32 (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
Nov-24-2020 14:04:52 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYN	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Time (US & Canada)			DROME CORONAVIRUS 2	
Nov-24-2020 14:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-26-2020 08:23:32 (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
Nov-24-2020 14:04:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry
Nov-24-2020 14:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-26-2020 08:23:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Dec-11-2020 03:51:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-09-2020 08:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Dec-09-2020 08:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry
Dec-08-2020 04:55:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please verify and provide missing data at

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

				Trade Name field appropriately.
Nov-24-2020 14:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-26-2020 08:23:32 (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
Nov-24-2020 14:04:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> POSITIVE	Initial Entry
Nov-24-2020 14:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-26-2020 08:23:32 (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
Nov-24-2020 14:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-26-2020 08:23:32 (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-17-2020 07:29:46	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo	Response satisfies query

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)			sed	
Dec-16-2020 07:56:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error
Dec-16-2020 07:56:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : NALT Unkn own	Transcription Error
Dec-16-2020 00:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Open ed	DM1: Response is updated as 'Unknown NALT', please consider updating response to NALT Unknown as mentioned in eCRF completion requirement.
Dec-15-2020 10:19:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	New Information
Dec-15-2020 10:19:40 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> :	New Information

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Central Time (US & Canada)			Unkn own NALT	
Dec-15-2020 02:31:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Open ed	DM: Please indicate whether the test was conducted in a CLIA- certified laboratory or by a laboratory accredited by the ISO 15189 by including the text "CLIA- certified lab" or "ISO 15189" in the response to this particular field.
Dec-14-2020 10:06:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error
Dec-14-2020 10:06:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : SAR SCoV 2 RN A	Transcription Error
Dec-11-2020 06:20:01 (UTC-06:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Op ened	sar scov rna qualitative naat is not

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/20/2020  
**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
**Form Version:** 06-Jul-2020 21:54  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1114  
**Site Name:** (1114) Alliance for Multispecialty Research Inc  
**Subject No:** 11141075  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:58

Central Time (US & Canada)				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, please provide clarification. (b) (4)
Dec-09-2020 08:59:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : SAR SCoV RNA Qualitative NAA T	Transcription Error
Dec-09-2020 08:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : SAR SCoV RNA Qulita v	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Nov-24-2020 14:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> :	Initial Entry
Oct-26-2020 08:23:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not A pplica ble	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-26-2020 08:24:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-26-2020 08:24:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-26-2020 08:24:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Oct-26-2020 08:24:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020**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:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-21-2020 10:40:49 (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-21-2020 10:40:49 (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
Oct-21-2020 10:41:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 10:40:49 (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-21-2020 10:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Oct-21-2020 10:41:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP5G32	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-21-2020 10:41:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5G32	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Oct-26-2020 08:21:40 (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
Oct-26-2020 08:21:40 (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
Oct-26-2020 08:21:40 (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
Oct-26-2020 08:21:40 (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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-26-2020 08:21:40 (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
Oct-26-2020 08:21:40 (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
Nov-24-2020 14:06:10 (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> YES <i>Number of Visits or Contacts:</i> 1	New Information
Oct-26-2020 08:21:40 (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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

**I.c Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Oct-26-2020 08:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

**I.c Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Nov-24-2020 14:06:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts</i> :  1	New Information
Oct-26-2020 08:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Oct-26-2020 08:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-26-2020 08:21:40 (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
Oct-26-2020 08:21:40 (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
Oct-26-2020 08:21:40 (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

***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-26-2020 08:21:40 (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
Oct-26-2020 08:21:40 (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 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

*1.f*

Date	Location	User	Value	Reason
Oct-26-2020 08:21:40 (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

*1.f Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Oct-26-2020 08:21:40 (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
Oct-26-2020 08:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 08:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-26-2020 08:26:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Dec-12-2020 06:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Dec-09-2020 09:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-09-2020 09:01:06 (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:  Nov/17/2020	New Information
Dec-08-2020 10:37:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Medical monitor: Since local laboratory SARS-CoV-2 NAAT test result was positive on 17Nov2020 please consider updating the diagnosis as "COVID-19 illness"

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020**Form:** ILLNESS DETAILS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Dec-08-2020 10:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Dec-08-2020 09:47:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Medical monitor: Since local and central laboratory SARS-CoV-2 NAAT result was positive on 17Nov2020 please consider updating the diagnosis as "COVID-19 illness"
Oct-26-2020 08:26:27 (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
Oct-26-2020 08:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-26-2020 08:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	New Information
Oct-26-2020 08:26:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Per CRF CRs Section 8.33.5, please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on SOD CRF. Please review and update as appropriate.
Oct-26-2020 08:26:38	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	0	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

**Form:** VITAL SIGNS - COVID - Audit Trail

**Form Version:** 21-Aug-2020 02:50

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Oct-21-2020 10:57:25 (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 Oct/20/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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**1. Date:**

Date	Location	User	Value	Reason
Oct-21-2020 10:57:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-21-2020 10:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 12 4 <b>Diastolic::</b> 82 <b>Respiratory Rate in respi</b> 16 <b>rations/minute:</b> <b>Heart Rate in beats/minu</b> 74 <b>te:</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-21-2020 10:57:25 (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
Oct-21-2020 10:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 124	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Oct/20/2020

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

**Form Version:** 21-Aug-2020 02:50

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

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Oct-21-2020 10:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 82	Initial Entry
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**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Oct-21-2020 10:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 16	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Oct-21-2020 10:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 74	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**I. Date of Visit**

Date	Location	User	Value	Reason
Feb-16-2021 12:40:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-16-2021 08:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Form Level comment is removed; ILL SEVERE left blank since there was not associated significant renal, hepatic or neurological dysfunction as part of their potential COVID-19 illness
Feb-15-2021 17:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Please remove the FORM Level comment from the ILL SEVERE form and update as per CCGs 8.34 else clarify
Jan-06-2021 08:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-06-2021 08:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/04/2021  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1114  
**Subject No:** 11141075  
**Generated By:** (b) (4)  
**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1114) Alliance for Multispecialty Research Inc  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58

				Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-06-2021 08:20:22 (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.
Jan-06-2021 08:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/4/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 08:20:22 (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 Jan/04/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/4/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/28/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Mar-10-2021 14:56:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Feb/16/2021	Transcription Error
Jan-06-2021 08:21:59 (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
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> YES	Initial Entry

**4.a Symptoms:**

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form Version:** 10-Dec-2020 02:29**Site No:** 1114**Subject No:** 11141075**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (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
Jan-06-2021 08:21:28 (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
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW OR INCRE : ASSED COUGH Symptom YES Present:	Initial Entry

**4.b Symptoms:**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COU GH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.c**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> YES	Initial Entry
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**4.c Symptoms:**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**4.d Symptoms:**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (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
Jan-06-2021 08:21:28 (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
Jan-06-2021 08:21:59 (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> YES	Initial Entry
Jan-06-2021 08:21:28 (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>	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**4.e Symptoms:**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUS CLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Jan-07-2021 15:52:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW LOSS OF T <b>s:</b> ASTE OR SMEL L <b>Symptom</b> NO <b>Present:</b>	Transcription Error
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW LOSS OF T <b>s:</b> ASTE OR SMEL L <b>Symptom</b> YES <b>Present:</b>	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58**4.f Symptoms:**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR S MELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Jan-08-2021 08:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-07-2021 15:52:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-07-2021 15:52:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Jan-07-2021 14:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Data does not match source
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREA SED SORE THRO AT <b>Symptom Present:</b> NO	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**4.g Symptoms:**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (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
Jan-06-2021 08:21:28 (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
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHE A <b>Symptom Presen t:</b> NO	Initial Entry

**4.h Symptoms:**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (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
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Not Complete

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Jan-07-2021 15:53:16 (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	Transcription Error
Jan-06-2021 08:21:28 (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> YES	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**4.i Symptoms:**

Date	Location	User	Value	Reason
Jan-06-2021 08:21:28 (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
Jan-08-2021 08:45:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-07-2021 15:53:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-07-2021 15:53:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Jan-07-2021 14:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Data does not match source
Jan-06-2021 08:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-06-2021 15:19:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - O</b> Nasal Conge <b>ther:</b> stion	Changed Information
Jan-06-2021 08:21:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Othe</b> Congestio <b>r:</b> n	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Jan-06-2021 19:00:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Jan-06-2021 15:19:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-06-2021 15:19:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nasal Co ngestion	Changed Information
Jan-06-2021 09:03:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify CONGESTION as follows...The term is incomplete. Are you reporting NASAL CONGESTION? SINUS CONGESTION? HEPATIC CONGESTION? Other? Please update the verbatim term to clarify. Thank you.
Jan-06-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b>	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Not Complete

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

08:21:47 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	<b>ry:</b> Congesti on	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Feb-08-2021 15:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Feb-10-2021 12:16:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 08:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-10-2021 08:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/5/2021	Transcription Error
Feb-09-2021 12:05:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per Medical Records, Positive on Jan 5; please update or clarify.
Feb-08-2021 15:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry
Feb-08-2021 15:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-06-2021 08:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Feb-08-2021 15:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry
Feb-08-2021 15:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Jan-06-2021 08:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Feb-08-2021 15:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry
Feb-08-2021 15:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-06-2021 08:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Feb-08-2021 15:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYN DROME CORONAVIRUS 2	Initial Entry
Feb-08-2021 15:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-06-2021 08:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Feb-08-2021 15:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-08-2021 15:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-06-2021 08:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Feb-08-2021 15:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry
Feb-08-2021 15:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-06-2021 08:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Feb-08-2021 15:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> POSITIVE	Initial Entry
Feb-08-2021 15:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-06-2021 08:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-08-2021 15:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Reactive A	Initial Entry
Feb-08-2021 15:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-06-2021 08:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Feb-08-2021 15:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT Unknown	Initial Entry
Feb-08-2021 15:39:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Jan-06-2021 08:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-06-2021 08:23:52 (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 08:23:52 (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
Jan-07-2021 15:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/4/2021	Transcription Error
Jan-06-2021 08:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-06-2021 08:23:52 (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 08:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

			Jan/5/2021	
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**5.a**

Date	Location	User	Value	Reason
Jan-06-2021 08:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> CV26631	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-06-2021 08:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CV26631	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-06-2021 08:24:41 (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 08:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-06-2021 08:24:41 (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
Jan-06-2021 08:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Telehealth visit	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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*I.a*

Date	Location	User	Value	Reason
Jan-06-2021 08:24:53 (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> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Jan-06-2021 08:24:53 (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
Jan-06-2021 08:24:53 (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
Feb-10-2021 08:25:06 (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> YES <i>Number of Visits or Contacts:</i>  1	Transcription Error

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-08-2021 09:44:06 (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	New Information
Feb-08-2021 09:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENC Y ROOM <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 3	New Information
Jan-12-2021 10:43:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENC Y ROOM <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	New Information
Jan-06-2021 08:24:53 (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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-06-2021 08:24:53 (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
Feb-10-2021 12:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 08:25:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-10-2021 08:25:06 (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	Transcription Error
Feb-09-2021 12:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per Medical Records, subject visited ER on JAN 5. Please, update to YES, or clarify.
Feb-08-2021 09:44:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	New Information
Feb-08-2021 09:43:14 (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>  3	New Information
Jan-12-2021 10:43:33	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	YES <i>Number of Visits or Contacts:</i>  1	
Jan-06-2021 08:24:53 (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
Feb-10-2021 08:26:02 (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> YES <i>Number of Visits or Contacts:</i>  1	Transcription Error
Jan-06-2021 08:24:53 (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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-06-2021 08:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-10-2021 12:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 08:26:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-10-2021 08:26:02 (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	Transcription Error
Feb-09-2021 12:19:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per Medical Records, subject visited PCP before going to ER. Please, update to YES or clarify.
Jan-06-2021 08:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.d***

Date	Location	User	Value	Reason
Jan-06-2021 08:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

			<b>Occurrence of Visits or Contacts:</b>	
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***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-06-2021 08:24:53 (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
Jan-06-2021 08:24:53 (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
Jan-06-2021 08:24:53 (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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-06-2021 08:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATI ON	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-06-2021 08:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Jan-06-2021 08:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH ER <b>Occurrence of Visits o r Contacts:</b> NO	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-06-2021 08:24:53 (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
Jan-06-2021 08:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Date	Location	User	Value	Reason
Feb-09-2021 14:42:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-08-2021 09:52:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Feb-08-2021 09:22:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: As subject is hospitalized, please complete RESP TX, ILL SEVERE, OXYGEN, VASOPRESS, and IMAGING CRFs as applicable.
Jan-25-2021 12:15:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-25-2021 08:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject still hospitalized will gather information when subject gets released
Jan-22-2021 11:52:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Query: As this subject was hospitalized, please enter on the CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

				information.
Jan-12-2021 10:43:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Has the subject been in intensive care due to potential COVID-19 illness?  NO	New Information
Jan-06-2021 08:24:53 (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 Jan/04/2021

**Form:** HOSPITALIZATION DETAILS - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Jan-12-2021 10:44:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Jan-12-2021 10:44:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HOSPITALIZATION STATUS	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Jan-12-2021 10:44:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HOSPITAL	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Jan-12-2021 10:44:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/5/2021	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Feb-09-2021 14:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-08-2021 09:52:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-08-2021 09:52:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Discharge Date:  Jan/13/2021	Transcription Error

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-08-2021 09:23:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: Please record end date.
Jan-25-2021 12:16:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-25-2021 08:47:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject still hospitalized will gather information when subject gets released
Jan-22-2021 11:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Please record end date.
Jan-12-2021 10:44:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** RESPIRATORY TREATMENT - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Feb-10-2021 08:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Feb-10-2021 08:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry
Feb-10-2021 08:29:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-08-2021 09:48:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-08-2021 09:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Feb-10-2021 08:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> YES	Initial Entry
Feb-10-2021 08:29:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-08-2021 09:48:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-08-2021 09:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:53**Form Status:** Data Complete, Frozen**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-10-2021 12:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 08:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-10-2021 08:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HIGH FLOW OXYGEN THE RAPY	Initial Entry
Feb-10-2021 08:29:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-09-2021 12:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per Medical Records subject was on Ventolin puff during hospital stay. Please, update or clarify.
Feb-08-2021 09:48:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-08-2021 09:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Feb-10-2021 08:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HIGH FLOW OXYGEN THE RAPY	Initial Entry
Feb-10-2021 08:29:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-08-2021 09:48:41	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
Feb-08-2021 09:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Feb-10-2021 08:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/5/2021	Initial Entry
Feb-10-2021 08:29:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-08-2021 09:48:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-08-2021 09:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Feb-10-2021 08:40:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Jan/11/2021	Transcription Error
Feb-10-2021 08:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Jan/7/2021	Initial Entry
Feb-10-2021 08:29:59 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Time (US & Canada)		(b) (4), (b) (6)		
Feb-08-2021 09:48:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-08-2021 09:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form:** ILLNESS DETAILS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Feb-10-2021 12:21:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 08:27:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-09-2021 11:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please updated COVID-19 Diagnosis to Yes since Positive result was updated.
Feb-01-2021 09:05:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILL NESS	Initial Entry
Jan-28-2021 10:23:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-06-2021 08:31:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILL NESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Feb-10-2021 08:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Ent ry:</b> YES <i>Respirat ory Illne ss Diagn osis:</i>	Transcription Error

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

			Covid-19 pneumonia	
			Date of Diagnosis:	
			Jan/7/2021	
Feb-01-2021 09:06:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-01-2021 09:05:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Feb-01-2021 09:05:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
Feb-01-2021 08:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	Clin: If no diagnosis, please enter No.
Jan-28-2021 10:23:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Canada)				
Jan-28-2021 10:23:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Ent ry:</b>	Transcription Error
Jan-22-2021 15:25:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: Diagnosis of COVID-19 (or similar) should only be recorded if subject is symptomatic and has a positive local swab recorded in COVID TEST CRF. See CRF CRs Section 8.33.3 for details.
Jan-12-2021 18:20:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Jan-12-2021 13:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-12-2021 13:18:25 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Ent ry:</b> YES <i>Respirat ory Illne</i>	Changed Information

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/04/2021  
**Form:** ILLNESS DETAILS - eCRF Audit Trail History  
**Form Version:** 06-Jul-2020 21:52  
**Form Status:** Data Complete, Frozen, Not Complete  
**Site No:** 1114  
**Site Name:** (1114) Alliance for Multispecialty Research Inc  
**Subject No:** 11141075  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:58

Canada)			<i>ss Diagn osis:</i>  COVI D-19 P neumo nia  Date of Diagnosi s:  Jan/5/2 021	
Jan-12-2021 13:03:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify COVID PNEUMONIA as follows...The term appears incomplete. Are you reporting COVID-19 PNEUMONIA? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate. Thank you.
Jan-12-2021 10:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Ent ry:</b> YES <i>Respirat ory Illne ss Diagn osis:</i>  COVI D Pnue monia	New Information

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Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Not Complete

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

			Date of Diagnosis:  Jan/5/2021	
Jan-06-2021 08:31:46 (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
Jan-06-2021 08:32:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry
Jan-06-2021 08:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-06-2021 08:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-06-2021 08:31:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Per CRF CRs Section 8.33.5, please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on SOD CRF. Please review and update as appropriate.
Jan-06-2021 08:31:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** ILLNESS DETAILS - SEVERE - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Feb-08-2021 09:50:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Feb-18-2021 08:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-18-2021 08:18:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-17-2021 13:22:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE COVID-19 ILLNESS	Initial Entry
Feb-16-2021 08:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 14:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-10-2021 08:28:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-08-2021 09:50:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE COVID-19 ILLNESS	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Feb-18-2021 15:22:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 08:20:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-18-2021 08:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-18-2021 05:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	If this assessment was not done, then kindly remove all entered data using the eraser icon. Once all entered data has been removed, an option to tick Not Done becomes available. Please update or clarify.
Feb-17-2021 13:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject had none of these diagnosis.
Feb-16-2021 23:58:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review the form and update the missing data with yellow background.
Feb-16-2021 08:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 14:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-10-2021 08:28:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-08-2021 16:35:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Feb-18-2021 08:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-18-2021 08:18:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-18-2021 01:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-17-2021 13:23:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	NA, subject not diagnosed with any of these Severe COVID Illness.
Feb-17-2021 13:22:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Was a diagnosis obtained?" is No. Please review and update as appropriate.
Feb-17-2021 13:22:13 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

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**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

(US & Canada)				
Feb-16-2021 08:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 14:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-11-2021 14:29:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Feb-11-2021 14:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-11-2021 13:48:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	Clin: Please add FORM LEVEL comment of Not Applicable. Please refer to CRF CRs Section 4.10 for details.
Feb-10-2021 08:28:38 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

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

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**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

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

**Generated Time (GMT):** 29-Mar-2021 10:58

(US & Canada)				
Feb-10-2021 08:28:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-09-2021 14:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: Please record COVID-19 Pneumonia on ILL POTEN CRF instead. Per CRF CRs Section 8.34, this CRF should only be completed if a participant had significant renal, hepatic or neurological dysfunction as part of their potential COVID-19 illness.
Feb-08-2021 18:09:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Feb-08-2021 15:39:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-08-2021 15:39:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Diagnosis:</i>  Covid-19 Pneumonia  Start Date:  Dec/28/2020  Ongoing?:  YES	New Information
Feb-08-2021 12:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify COVID PNEUMONIA as follows...The term appears incomplete. Are you reporting COVID-19 PNEUMONIA? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate. Thank you.
Feb-08-2021 09:50:41 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Diagnosis</i>	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

(US & Canada)			is:	
			Covid Pneum onia	
			Start Da te:	
			Dec/2 8/2020	
			Ongoin g?:	
			YES	

4. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-18-2021 08:19:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-16-2021 08:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 14:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-10-2021 08:29:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-08-2021 09:50:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

**Form Version:** 21-Aug-2020 02:49

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

Form: LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-08-2021 16:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Feb-08-2021 16:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Newton Medical Center Labora tory 600 Medical Center Dr. Newton Kansas 67114	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-08-2021 16:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Feb-08-2021 16:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-08-2021 16:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defi 329 ned Identifier :	Transcription Error

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form Version:** 21-Aug-2020 02:49**Site No:** 1114**Subject No:** 11141075**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

			<b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> 54.8 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 0  High 9  Unit mg/L	
Feb-08-2021 16:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> 329 : <b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> high <b>Not Done::</b> <b>Lab Normal Range:</b> Low 0  High 9  Unit mg/L	New Information
Feb-08-2021 16:15:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> 329 : <b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> high <b>Not Done::</b>	Transcription Error

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form Version:** 21-Aug-2020 02:49**Site No:** 1114**Subject No:** 11141075**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

			<b>Lab Normal Range:</b> <i>High</i> 54.8  <i>Unit</i> mg/L	
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> 329 : <b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> High <b>Not Done::</b> <b>Lab Normal Range:</b> <i>High</i> 54.8  <i>Unit</i> mg/L	Initial Entry

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C Reactive Protein_PX329	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Feb-08-2021 16:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 54.8	Transcription Error

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
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CHEMISTRY - eCRF Audit Trail History

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Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Feb-08-2021 16:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-08-2021 16:15:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> high	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> High	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Feb-08-2021 16:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 9  <i>Unit</i> mg/L	New Information
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>High</i> 54.8  <i>Unit</i> mg/L	Initial Entry

5.b

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form Version:** 21-Aug-2020 02:49**Site No:** 1114**Subject No:** 11141075**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-08-2021 16:19:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alanine Amino transferase_PX 30 <b>Result::</b> 59 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 1  High 35  Unit U/L	Transcription Error
Feb-08-2021 16:18:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alanine Amino transferase_PX 30 <b>Result::</b> High <b>Not Done::</b> <b>Lab Normal Range:</b> Low 1  High 35  Unit U/L	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Site No:** 1114

**Subject No:** 11141075

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

**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Status:** Data Complete, Frozen

**Site Name:** (1114) Alliance for Multispecialty Research Inc

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**Generated Time (GMT):** 29-Mar-2021 10:58

			<b>Test::</b> Alanine Amino transferase_PX 30	
			<b>Result::</b> High	
			<b>Not Done::</b>	
			<b>Lab Normal</b> <i>Low</i>	
			<b>Range:</b> 49	
			<i>High</i>	
			67	
			<i>Unit</i>	
			U/L	

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Alanine Aminotransferase_PX 30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Feb-08-2021 16:19:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 59	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> High	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Feb-08-2021 16:18:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low 1  High 35  Unit U/L	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low 49	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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				High 67
				Unit U/L

**5.c**

Date	Location	User	Value	Reason
Feb-08-2021 16:19:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Aspartate Aminotransferase_P X28 <b>Result::</b> 64 <b>Not Done:</b> <b>Lab Normal Range:</b> Low 14  High 36  Unit U/L	Transcription Error
Feb-08-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Aspartate Aminotransferase_P X28 <b>Result::</b> High <b>Not Done:</b>	Transcription Error

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Subject No:** 11141075

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

**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Status:** Data Complete, Frozen

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			<b>Lab Normal</b> <i>Low</i> <b>Range:</b> 14  <i>High</i> 36  <i>Unit</i> U/L	
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Aspartate Aminotransferase_P X28 <b>Result::</b> High <b>Not Done::</b> <b>Lab Normal</b> <i>Low</i> <b>Range:</b> 31  <i>High</i> 50  <i>Unit</i> U/L	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
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5.c Sponsor ID:

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aspartate Aminotransferase_P X28	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Feb-08-2021 16:19:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 64	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> High	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Feb-08-2021 16:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>  <i>Low</i> 14  <i>High</i> 36  <i>Unit</i> U/L	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 31	Initial Entry

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**Header Text:** c4591001

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**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

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**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

				<i>High</i> 50
				<i>Unit</i> U/L

**5.d**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-08-2021 16:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> 95 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 38  <i>High</i> 126  <i>Unit</i> U/L	Transcription Error
Feb-08-2021 16:19:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> 95 <b>Not Done::</b>	Transcription Error

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Site No:** 1114

**Subject No:** 11141075

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

**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Status:** Data Complete, Frozen

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

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			<b>Lab Normal Range:</b> <i>Low</i> 77  <i>High</i> 95  <i>Unit</i> U/L	
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 35 <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> Normal <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 77  <i>High</i> 95  <i>Unit</i> U/L	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
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Site Name: (1114) Alliance for Multispecialty Research Inc

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Subject Initials: ---

Generated By: (b) (4)

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Feb-08-2021 16:19:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 95	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Normal	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Feb-08-2021 16:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low 38  High 126  Unit U/L	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low 77	Initial Entry

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**Subject Initials:** ---

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			High 95	
			Unit U/L	

5.e

Date	Location	User	Value	Reason
Feb-08-2021 16:20:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 21 <b>Test::</b> Bilirubin_ PX21 <b>Result::</b> 0.4 <b>Not Done::</b> <b>Lab Normal Range:</b> Low .2  High 1.3  Unit mg/dL	Transcription Error
Feb-08-2021 16:20:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 21 <b>Test::</b> Bilirubin_ PX21 <b>Result::</b> 0.4 <b>Not Done::</b>	Transcription Error

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			<b>Lab Normal Range:</b> <i>Low</i> .2  <i>High</i> .4  <i>Unit</i> mg/dL	
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined</b> 21 <b>Identifier:</b> <b>Test::</b> Bilirubin_ PX21 <b>Result::</b> Normal <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> .2  <i>High</i> .4  <i>Unit</i> mg/dL	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

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5.e Sponsor ID:

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Feb-08-2021 16:20:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.4	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Normal	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Feb-08-2021 16:20:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low .2  High 1.3  Unit mg/dL	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low .2	Initial Entry

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			High .4	
			Unit mg/dL	

5.f

Date	Location	User	Value	Reason
Feb-09-2021 08:46:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> 47 : <b>Test::</b> Blood Urea Ni trogen_PX47 <b>Result::</b> 16 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 7  High 17  Unit mg/dL	Transcription Error

Header Text: c4591001

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5.f

Date	Location	User	Value	Reason
Feb-08-2021 16:21:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> 16 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 7  High 17	Transcription Error
Feb-08-2021 16:20:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> 16 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 16  High 25	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> High	Initial Entry

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			<b>Not Done::</b>	
			<b>Lab Normal</b> <i>Low</i>	
			<b>Range:</b> 16	
			<i>High</i>	
			25	

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5.f Sponsor ID:

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Feb-09-2021 12:39:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 08:46:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Feb-09-2021 01:55:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Please update Unit in Lab Normal Range field. Else, clarify.
Feb-08-2021 16:22:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-08-2021 16:20:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 16	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high

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				or Unit) is missing. Please correct or confirm.
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> High	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Feb-09-2021 08:46:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 7  <i>High</i> 17  <i>Unit</i> mg/dL	Transcription Error
Feb-08-2021 16:21:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 7  <i>High</i> 17	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 16  <i>High</i> 25	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-08-2021 16:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Define 48 <b>d Identifier:</b>	Transcription Error

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**Subject No:** 11141075  
**Generated By:** (b) (4)

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**Site Name:** (1114) Alliance for Multispecialty Research Inc  
**Subject Initials:** ---  
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			<b>Test::</b> Creatinine _PX48 <b>Result::</b> .8 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> .7  <i>High</i> 1.2  <i>Unit</i> mg/dL	
Feb-08-2021 16:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 48 <b>Test::</b> Creatinine _PX48 <b>Result::</b> Nomal <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> .7  <i>High</i> 1.2  <i>Unit</i> mg/dL	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 48 <b>Test::</b> Creatinine _PX48 <b>Result::</b> Nomal <b>Not Done::</b>	Initial Entry

**Header Text:** c4591001

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			<b>Lab Normal Range:</b>	<i>Low</i> .7	
				<i>High</i> .9	
				<i>Unit</i> mg/dL	

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Feb-08-2021 16:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> .8	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nomal	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Feb-08-2021 16:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low .7  High 1.2  Unit mg/dL	Transcription Error
Feb-08-2021 16:15:01 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low	Initial Entry

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Time (US & Canada)	(b) (4), (b) (6)	.7	
		<i>High</i>	
		.9	
		<i>Unit</i>	
		mg/dL	

**Header Text:** c4591001

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**Subject No:** 11141075

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Newton Medical Center Labora tory 600 Medical Center Dr. Newton Kansas 67114	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hemoglobi n_PX1	Initial Entry

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

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			<b>Result::</b> 13.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 12 <i>High</i> 16 <i>Unit</i> g/dL	
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**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 13.9	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 12	Initial Entry

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			<i>High</i> 16	
			<i>Unit</i> g/dL	

**5.b**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined I 2            identifier:</b> <b>Test::</b> Hematocrit _PX2 <b>Result::</b> 42.4 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 36  <i>High</i> 46  <i>Unit</i> %	Initial Entry

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**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 42.4	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 36  <i>High</i> 46  <i>Unit</i> %	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined 3</b>	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Form Version:** 21-Aug-2020 02:51

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
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**Form Status:** Data Complete, Frozen

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

			<b>Identifier:</b>	
			<b>Test::</b>	Erythrocyte s_PX3
			<b>Result::</b>	5.07
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b>	<i>Low</i> 4  <i>High</i> 5.2  <i>Unit</i> /uL

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
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**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

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

**Generated Time (GMT):** 29-Mar-2021 10:58

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 5.07	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 4  <i>High</i> 5.2  <i>Unit</i> /uL	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Feb-08-2021 16:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined 5</b>	Transcription Error

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Form Version:** 21-Aug-2020 02:51

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
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**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

			<b>Identifier:</b> <b>Test::</b> Platelets_ PX5 <b>Result::</b> 239 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 130  <i>High</i> 400  <i>Unit</i> 10 <sup>6</sup> /cu mm	
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_ PX5 <b>Result::</b> 239 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 130  <i>High</i> 400	Initial Entry

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Feb-08-2021 16:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 239	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Feb-08-2021 16:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 130 <i>High</i>	Transcription Error

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/04/2021  
**Form Version:** 21-Aug-2020 02:51  
**Site No:** 1114  
**Subject No:** 11141075  
**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen  
**Site Name:** (1114) Alliance for Multispecialty Research Inc  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58

			400	
			<i>Unit</i> 10 <sup>6</sup> /cu mm	
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 130  <i>High</i> 400	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Leukocytes _PX7 <b>Result::</b> <b>Not Done::</b> NOT DON E <b>Lab Normal Range:</b>	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/04/2021  
**Form Version:** 21-Aug-2020 02:51  
**Site No:** 1114  
**Subject No:** 11141075  
**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen  
**Site Name:** (1114) Alliance for Multispecialty Research Inc  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Feb-08-2021 16:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Define 608 d Identifier: Test:: Neutrophils _PX608 Result:: 4.5 Not Done::	Transcription Error

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Site No:** 1114

**Subject No:** 11141075

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
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**Form Status:** Data Complete, Frozen

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

			<b>Lab Normal Range:</b> <i>Low</i> 1.8  <i>High</i> 7.7  <i>Unit</i> 10 <sup>6</sup> /cu m m	
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils _PX608 <b>Result::</b> 4.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1.8  <i>High</i> 7.7	Initial Entry

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 608	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Neutrophils_PX608	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Feb-08-2021 16:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4.5	Initial Entry

**5.f LNMT**

Date	Location	User	Value	Reason
Feb-08-2021 16:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 1.8  <i>High</i>	Transcription Error

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/04/2021  
**Form Version:** 21-Aug-2020 02:51  
**Site No:** 1114  
**Subject No:** 11141075  
**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen  
**Site Name:** (1114) Alliance for Multispecialty Research Inc  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58

			7.7	
			<i>Unit</i> 10 <sup>6</sup> /cu mm	
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 1.8  <i>High</i> 7.7	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0  <i>High</i> 4  <i>Unit</i> %	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.g Sponsor ID:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 4  <i>Unit</i> %	Initial Entry

5.h

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined 612</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
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**Form Status:** Data Complete, Frozen

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

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			<b>Identifier:</b>	
			<b>Test::</b>	Monocytes_ PX612
			<b>Result::</b>	6
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b>	<i>Low</i> 0
				<i>High</i> 9
				<i>Unit</i> %

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Header Text: c4591001

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Form Status: Data Complete, Frozen

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Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.h Sponsor ID:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 6	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>  <i>Low</i> 0  <i>High</i> 9  <i>Unit</i> %	Initial Entry

5.i

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined 610	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/04/2021  
**Form Version:** 21-Aug-2020 02:51  
**Site No:** 1114  
**Subject No:** 11141075  
**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen  
**Site Name:** (1114) Alliance for Multispecialty Research Inc  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58

			<b>Identifier:</b> <b>Test::</b> Basophils_P X610 <b>Result::</b> 0 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0  <i>High</i> 2  <i>Unit</i> %
--	--	--	---

**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 610	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Basophils_PX610	Initial Entry

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Header Text: c4591001

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**5.i Result:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0  <i>High</i> 2  <i>Unit</i> %	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Feb-08-2021 16:33:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b>  <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> 0.8 <b>Not Done::</b>	Transcription Error

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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**Form Version:** 21-Aug-2020 02:51

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
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**Form Status:** Data Complete, Frozen

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

			<b>Lab Normal Range:</b> <i>Low</i> 1  <i>High</i> 4.8  <i>Unit</i> 10 <sup>6</sup> /cu m m	
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> 0.8 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1  <i>High</i> 4.8	Initial Entry

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
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Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 611	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lymphocytes_PX611	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Feb-08-2021 16:33:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.8	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Feb-08-2021 16:33:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 1 <i>High</i>	Transcription Error

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

**Site No:** 1114

**Subject No:** 11141075

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

			4.8	
			<i>Unit</i> 10 <sup>6</sup> /cu mm	
Feb-08-2021 16:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 1  <i>High</i> 4.8	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** VITAL SIGNS - COVID - Audit Trail

**Form Version:** 21-Aug-2020 02:50

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Feb-08-2021 16:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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**1. Date:**

Date	Location	User	Value	Reason
Feb-08-2021 16:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-08-2021 16:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 11 8 <b>Diastolic::</b> 79 <b>Respiratory Rate in respi</b> 19 <b>rations/minute:</b> <b>Heart Rate in beats/minu</b> 93 <b>te:</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Feb-08-2021 16:35:26 (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
Feb-08-2021 16:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 118	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-08-2021 16:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 79	Initial Entry
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**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Feb-08-2021 16:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 19	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Feb-08-2021 16:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 93	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Feb-08-2021 15:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail  
History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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**1. Date:**

Date	Location	User	Value	Reason
Feb-10-2021 12:19:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 08:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-10-2021 08:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/5/2021	Transcription Error
Feb-09-2021 16:04:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please consider updating to January or calrify.
Feb-08-2021 15:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-08-2021 15:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 86.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Feb-08-2021 15:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail  
History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-08-2021 15:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 86.0	Initial Entry
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090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Feb-08-2021 09:51:06 (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
Feb-08-2021 09:51:06 (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
Feb-09-2021 16:03:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Not applicable, this was not done per records.
Feb-09-2021 12:33:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per Medical Records on O2 from 05JAN to 11JAN. Please update or clarify.
Feb-08-2021 09:51:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Feb-08-2021 09:51:36 (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
Feb-08-2021 09:51:36 (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
Feb-08-2021 09:51:36 (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
Feb-08-2021 09:51:36 (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
Feb-08-2021 09:51:36 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -  
eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Time (US & Canada)	(b) (4), (b) (6)
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**6. Ongoing?**

Date	Location	User	Value	Reason
Feb-08-2021 09:51:36 (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 Jan/04/2021

**Form:** IMAGING - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Feb-10-2021 08:34:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

**Form:** IMAGING - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Feb-10-2021 08:36:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-10-2021 08:34:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry
Feb-09-2021 14:23:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-08-2021 09:52:03 (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
Feb-10-2021 08:34:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHEST	Initial Entry
Feb-09-2021 14:23:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-08-2021 09:52:03 (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
Feb-10-2021 12:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 08:34:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled  
Visit on Jan/04/2021**Form:** IMAGING - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:53**Form Status:** Data Complete, Frozen**Site No:** 1114**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject No:** 11141075**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-10-2021 08:34:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> X-RAY	Initial Entry
Feb-09-2021 14:23:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-09-2021 12:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per Medical Records Chest-X-Ray and CT were done during ER and Hospital stay.
Feb-08-2021 09:52:03 (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
Feb-10-2021 08:34:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> INDETERMINATE	Initial Entry
Feb-09-2021 14:23:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-08-2021 09:52:03 (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 Jan/04/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-10-2021 08:37:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/7/2021	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Feb-10-2021 08:36:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHEST	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Feb-10-2021 08:36:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CT SCAN	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Feb-10-2021 08:36:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ABNORMAL <i>If abnormal, specify findings:</i>  Pulmonary findings consist nt with COVID-19 pneumo nia of moderate severity. De veloping bacterial superinfe ction in the lower lobes can not be excluded.	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Nov/23/2020

**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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Date of Visit**

Date	Location	User	Value	Reason
Nov-24-2020 08:27:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/23/2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-24-2020 08:27:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Nov/23/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1114**Subject No:** 11141075**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-24-2020 08:42:33 (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
Nov-24-2020 08:42:33 (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
Nov-24-2020 08:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-24-2020 08:42:33 (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.
Nov-24-2020 08:42:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/23/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Nov/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Nov-24-2020 08:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPR6ZW</b>	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-24-2020 08:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPR6ZW	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-24-2020 08:44:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPR6ZX</b>	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-24-2020 08:44:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPR6ZX	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-24-2020 08:45:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPVPLZ</b>	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-24-2020 08:45:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVPLZ	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 -  
Unscheduled Visit on Feb/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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-05-2021 18:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-05-2021 18:19:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_B1	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 2 -  
Unscheduled Visit on Feb/05/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1114**Subject No:** 11141075**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1114) Alliance for Multispecialty Research Inc**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-05-2021 18:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-05-2021 18:19:45 (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
Feb-05-2021 18:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 18:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-05-2021 18:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/5/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 -  
Unscheduled Visit on Feb/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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

Feb-05-2021 18:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM3CKB	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-05-2021 18:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM3CKB	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Feb-05-2021 18:20:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM3CKC	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-05-2021 18:20:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM3CKC	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-05-2021 18:22:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPVPRX	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-05-2021 18:22:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVPRX	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Oct-12-2020 09:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-12-2020 09:11:23 (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-12-2020 09:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Oct-22-2020 11:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Oct-21-2020 11:09:39 (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: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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1. Category:

Date	Location	User	Value	Reason
Oct-21-2020 11:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-21-2020 11:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-22-2020 18:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-22-2020 11:28:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	COVID Illness will be deleted from AE
Oct-22-2020 09:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Query: COVID illness information is recorded in COVID Illness Visit and not AE

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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				CRF.
Oct-21-2020 22:13:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Cl osed	Discrepancy has been closed.
Oct-21-2020 16:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: A nswered	corrected
Oct-21-2020 16:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Covid-19 Il lness A	corrected
Oct-21-2020 14:32:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: O pened	Clarify COVID ILLNESS as follows...The term appears incomplete. Are you reporting COVID-19 ILLNESS? If so, edit the term as such. Otherwise, clarify and edit the term as appropriate. Thank you.
Oct-21-2020 11:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Covid Illne ss	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-21-2020 11:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/18/2020 09:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-21-2020 11:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-21-2020 11:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Oct-21-2020 11:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1114

Subject No: 11141075

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Frozen

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject Initials: ---

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

Oct-21-2020 11:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-21-2020 11:09:39 (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>  Viral Infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-21-2020 11:09:39 (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
Oct-21-2020 11:09:39 (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
Oct-21-2020 11:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

**Site No:** 1114

**Subject No:** 11141075

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

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

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

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Oct-21-2020 11:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RE SOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 11:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

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Date	Location	User	Value	Reason
Mar-05-2021 13:31:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Feb-11-2021 14:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Date	Location	User	Value	Reason
Mar-09-2021 08:40:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Mar-09-2021 08:39:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Mar-09-2021 08:39:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Feb-11-2021 14:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Date	Location	User	Value	Reason
Mar-09-2021 08:40:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Feb-11-2021 14:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Mar-09-2021 08:41:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Feb-11-2021 14:41:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Date	Location	User	Value	Reason
Mar-09-2021 08:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Feb-11-2021 15:10:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Date	Location	User	Value	Reason
Mar-09-2021 08:42:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Feb-11-2021 15:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Date	Location	User	Value	Reason
Mar-09-2021 08:42:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Feb-11-2021 15:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Date	Location	User	Value	Reason
Mar-09-2021 08:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Feb-11-2021 15:34:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

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

**Form Status:**

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**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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Date	Location	User	Value	Reason
Mar-09-2021 08:43:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Feb-11-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

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

**Form Status:**

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Mar-09-2021 08:44:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Feb-11-2021 17:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

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**Generated Time (GMT):** 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Mar-09-2021 08:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Feb-11-2021 17:20:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-04-2021 08:22:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-04-2021 08:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CORTICOSTEROIDS	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 08:22:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

**4. Medication:**

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

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Date	Location	User	Value	Reason
Mar-04-2021 13:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-04-2021 08:22:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-04-2021 08:22:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 11:57:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINQUERY: Query response notes med was given for COVID treatment. However, medications should only be reported on this CRF if they are PROHIBITED. As this medication does not meet the definition of prohibited, please verify it was entered in error.
Feb-26-2021 16:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Medication given during COVID treatment and recorded
Feb-26-2021 10:05:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Query response notes subject was taking Prednisone for COVID. However, as it was not taken for 14

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				days, please verify it does not meet the definition of a prohibited med per section 6.5.1 of the protocol. Please verify it was entered in error.
Feb-25-2021 19:26:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLINQUERY: Query response notes subject was taking Prednisone for COVID. However, as it was not taken for 14 days, please verify it does not meet the definition of a prohibited med per section 6.5.1 of the protocol. Please verify it was entered in error.
Feb-18-2021 11:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	Response satisfies query
Feb-17-2021 13:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Correct as entered, subject taking Prednisone for COVID Illness B which does not have an end date.
Feb-17-2021 07:52:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Prednisone intake was reported from 28 Dec till 01 Jan, however, an underlying medical

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				condition has not been captured in the AE log (last COVID symptom resolved on 14 Dec). Please review and update AE log, else clarify in query response. Thanks
Feb-11-2021 14:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Prednisone	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Mar-04-2021 08:22:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 40	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Mar-04-2021 08:22:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
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Mar-04-2021 08:22:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Mar-04-2021 08:22:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Mar-04-2021 08:23:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Dec/28/2020	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 08:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:31:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 11:26:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	COVID treatment removed as per query
Feb-11-2021 14:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-09-2021 13:31:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-09-2021 08:40:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-08-2021 05:29:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please inactivate all loglines if not required. Thank you.
Mar-04-2021 08:24:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 14:38:13 (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
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Mar-02-2021 11:26:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	COVID treatment removed as per query
Feb-11-2021 14:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Mar-04-2021 13:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 08:26:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-03-2021 10:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Name of Medication was removed for this medication that was not prohibited. However, the rest of the data remains. Please verify that all data for this medication was entered in error and update CRF accordingly.
Mar-02-2021 11:26:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	COVID treatment removed as per query

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Mar-02-2021 11:26:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	COVID treatment removed as per query
Mar-01-2021 18:20:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Query response notes medications given for COVID treatment. However, medications should only be reported if they are PROHIBITED. As these medications do not meet the definition of prohibited, please verify they were entered in error.
Feb-26-2021 16:20:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medication given during COVID treatment and recorded
Feb-26-2021 15:00:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Doxycycline is reported as a Prohibited Medication. However, this medication is not prohibited per protocol. Please verify it was entered in error and update CRF accordingly.
Feb-11-2021 14:37:42 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> doxycycline	Initial Entry

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Subject Initials: ---

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Time (US & Canada)

5. Dose:

Date	Location	User	Value	Reason
Mar-04-2021 08:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 100	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Mar-04-2021 08:24:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Mar-04-2021 08:24:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BID	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Mar-04-2021 08:25:08	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error

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**Subject Initials:** ---

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		
Feb-11-2021 14:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL	Initial Entry

**9. Start Date:**

Date	Location	User	Value	Reason
Mar-04-2021 08:25:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/28/2020	Initial Entry

**10. Ongoing?**

Date	Location	User	Value	Reason
Mar-04-2021 08:26:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Jan/6/2021	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-04-2021 08:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-04-2021 08:27:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CORTICOSTEROIDS	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 08:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

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Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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*Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Mar-04-2021 13:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-04-2021 08:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-04-2021 08:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 11:58:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINQUERY: Query response notes med was given for COVID treatment. However, medications should only be reported on this CRF if they are PROHIBITED. As this medication does not meet the definition of prohibited, please verify it was entered in error.
Feb-26-2021 16:21:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Medication given during COVID treatment and recorded
Feb-26-2021 10:08:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Query response notes subject was taking Prednisone for COVID.

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**Header Text:** c4591001

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**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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				However, as it was not taken for 14 days, please verify it does not meet the definition of a prohibited med per section 6.5.1 of the protocol. Please verify it was entered in error.
Feb-25-2021 19:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLINQUERY: Query response notes subject was taking Prednisone for COVID. However, as it was not taken for 14 days, please verify it does not meet the definition of a prohibited med per section 6.5.1 of the protocol. Please verify it was entered in error.
Feb-18-2021 11:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	participant is taking prednisone due to COVID, confirmed by data on COV ILL #2 eCRF
Feb-17-2021 13:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Correct as entered.
Feb-17-2021 07:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Prednisone intake was reported from 27 Jan till 31 Jan, however, an

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				underlying medical condition/AE has not been captured in the AE log. Please review and update AE log, else clarify in query response. Thanks
Feb-11-2021 14:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> prednisone	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Mar-04-2021 08:27:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 40	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Mar-04-2021 08:27:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Mar-04-2021 08:28:42 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

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Time (US & Canada)		(b) (4), (b) (6)		
Feb-11-2021 14:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Mar-04-2021 08:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Mar-04-2021 08:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/27/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 08:37:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Jan/31/2021	Initial Entry

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

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

Date	Location	User	Value	Reason
Mar-04-2021 08:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:41:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-04-2021 08:37:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 14:41:51 (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-04-2021 08:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:41:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

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*Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Mar-04-2021 13:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 08:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 08:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 12:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Query response notes med was given for COVID treatment. However, medications should only be reported on this CRF if they are PROHIBITED. As this medication does not meet the definition of prohibited, please verify it was entered in error.
Feb-26-2021 16:22:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medication given during COVID treatment and recorded
Feb-26-2021 14:59:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Aspirin is reported as a Prohibited Medication. However, this

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				medication is not prohibited per protocol. Please verify it was entered in error and update CRF accordingly.
Feb-11-2021 14:41:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aspirin	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Mar-04-2021 08:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:41:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 81	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Mar-04-2021 08:38:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 14:41:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Mar-04-2021 08:38:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

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Feb-11-2021 14:41:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> QD	Initial Entry
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8. Route:

Date	Location	User	Value	Reason
Mar-04-2021 08:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:41:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Mar-04-2021 08:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:41:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/13/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 08:39:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 14:41:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 08:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:10:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-04-2021 08:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Feb-11-2021 15:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 08:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:10:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

**4. Medication:**

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

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*Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Mar-04-2021 13:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 08:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 08:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 10:42:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Query response notes meds were given for COVID treatment. However, medications should only be reported on this CRF if they are PROHIBITED. As these medications do not meet the definition of prohibited, please verify they were entered in error.
Feb-26-2021 16:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medication given during COVID treatment and recorded
Feb-26-2021 15:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Ceftriaxone is reported as a Prohibited Medication.

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				However, this medication is not prohibited per protocol. Please verify it was entered in error and update CRF accordingly.
Feb-11-2021 15:10:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ceftriaxone	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Mar-04-2021 08:40:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:10:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Mar-04-2021 08:40:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:10:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> g	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Mar-04-2021 08:40:44 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error

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Time (US & Canada)		(b) (4), (b) (6)		
Feb-11-2021 15:10:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Mar-04-2021 08:40:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:10:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Mar-04-2021 08:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:10:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 08:44:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:10:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Jan/13/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 08:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-04-2021 08:44:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 15:12:28 (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-04-2021 08:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
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Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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*Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Mar-04-2021 13:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 08:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 08:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 10:43:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Query response notes meds were given for COVID treatment. However, medications should only be reported on this CRF if they are PROHIBITED. As these medications do not meet the definition of prohibited, please verify they were entered in error
Feb-26-2021 16:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medication given during COVID treatment and recorded
Feb-26-2021 15:02:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Remdesivir is reported as a Prohibited Medication.

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Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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				However, this medication is not prohibited per protocol. Please verify it was entered in error and update CRF accordingly.
Feb-11-2021 15:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> remdesivir	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Mar-04-2021 08:45:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 100	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Mar-04-2021 08:45:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Mar-04-2021 08:45:42 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Time (US & Canada)		(b) (4), (b) (6)		
Feb-11-2021 15:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Mar-04-2021 08:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Mar-04-2021 08:46:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 08:46:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Jan/9/2021	Initial Entry

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**Header Text:** c4591001

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**Site No:** 1114

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Mar-04-2021 08:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-04-2021 08:46:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 15:13:38 (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-04-2021 08:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

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Generated Time (GMT): 29-Mar-2021 10:58

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*Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Mar-04-2021 13:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 08:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 08:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 10:50:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Query response notes meds were given for COVID treatment. However, medications should only be reported on this CRF if they are PROHIBITED. As these medications do not meet the definition of prohibited, please verify they were entered in error
Feb-26-2021 16:22:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medication given during COVID treatment and recorded
Feb-26-2021 15:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Zithromax is reported as a Prohibited Medication.

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**Header Text:** c4591001

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**Subject Initials:** ---

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

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				However, this medication is not prohibited per protocol. Please verify it was entered in error and update CRF accordingly.
Feb-11-2021 15:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Zithromax	Initial Entry

**5. Dose:**

Date	Location	User	Value	Reason
Mar-04-2021 08:47:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 500	Initial Entry

**6. Dose Unit:**

Date	Location	User	Value	Reason
Mar-04-2021 08:47:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mg	Initial Entry

**7. Dose Frequency:**

Date	Location	User	Value	Reason
Mar-04-2021 08:48:10 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

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Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

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Time (US & Canada)		(b) (4), (b) (6)		
Feb-11-2021 15:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ONCE	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Mar-04-2021 08:52:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Mar-04-2021 08:53:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/5/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 08:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Jan/5/2021	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Mar-04-2021 08:55:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:34:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-04-2021 08:53:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 15:35:12 (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-04-2021 08:55:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:34:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

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Generated Time (GMT): 29-Mar-2021 10:58

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*Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Mar-04-2021 13:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 08:55:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 08:55:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 10:51:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Query response notes meds were given for COVID treatment. However, medications should only be reported on this CRF if they are PROHIBITED. As these medications do not meet the definition of prohibited, please verify they were entered in error
Feb-26-2021 16:22:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medication given during COVID treatment and recorded
Feb-26-2021 15:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Guaifenesin is reported as a Prohibited Medication.

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Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

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				However, this medication is not prohibited per protocol. Please verify it was entered in error and update CRF accordingly.
Feb-11-2021 15:34:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Guaifenesin	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Mar-04-2021 08:55:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1200	New Information
Feb-11-2021 15:34:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Mar-04-2021 08:55:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:17:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mg	Initial Entry

7. Dose Frequency:

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Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Date	Location	User	Value	Reason
Mar-04-2021 08:56:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:34:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BID	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Mar-04-2021 08:57:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:34:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Mar-04-2021 08:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:34:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/7/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 08:57:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:34:55	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

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

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

NO  
End Date:

Jan/13/2021

**Header Text:** c4591001

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

Date	Location	User	Value	Reason
Mar-04-2021 08:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-04-2021 08:57:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 15:36:43 (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-04-2021 08:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

*Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Mar-04-2021 13:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 08:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 08:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 10:51:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Query response notes meds were given for COVID treatment. However, medications should only be reported on this CRF if they are PROHIBITED. As these medications do not meet the definition of prohibited, please verify they were entered in error.
Feb-26-2021 16:23:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medication given during COVID treatment and recorded
Feb-26-2021 15:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Zofran is reported as a Prohibited Medication. However, this

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

				medication is not prohibited per protocol. Please verify it was entered in error and update CRF accordingly.
Feb-11-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Zofran	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Mar-04-2021 08:58:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Mar-04-2021 08:58:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Mar-04-2021 08:58:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
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Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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Feb-11-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ONCE	Initial Entry
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8. Route:

Date	Location	User	Value	Reason
Mar-04-2021 08:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Mar-04-2021 08:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/5/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 08:59:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:  Jan/5/2021	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
Audit Trail History

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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

Date	Location	User	Value	Reason
Mar-04-2021 09:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-04-2021 09:00:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 17:19:58 (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-04-2021 09:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
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Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

*Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Mar-04-2021 13:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 09:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 09:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 10:52:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Query response notes meds were given for COVID treatment. However, medications should only be reported on this CRF if they are PROHIBITED. As these medications do not meet the definition of prohibited, please verify they were entered in error.
Feb-26-2021 16:23:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medication given during COVID treatment and recorded
Feb-26-2021 15:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Ventolin HFA is reported as a Prohibited Medication.

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Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
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Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

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

				However, this medication is not prohibited per protocol. Please verify it was entered in error and update CRF accordingly.
Feb-11-2021 17:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ventolin HFA	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Mar-04-2021 09:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> .27	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Mar-04-2021 09:00:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> g	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Mar-04-2021 09:01:06 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
Audit Trail History

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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Time (US & Canada)		(b) (4), (b) (6)		
Feb-11-2021 17:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> QID	Initial Entry

**8. Route:**

Date	Location	User	Value	Reason
Mar-04-2021 09:01:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RESPIRATORY (INHALATI ON)	Initial Entry

**9. Start Date:**

Date	Location	User	Value	Reason
Mar-04-2021 09:01:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

**10. Ongoing?**

Date	Location	User	Value	Reason
Mar-04-2021 09:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Jan/13/2021	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
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**Form Version:** 22-Apr-2020 21:03

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

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

Date	Location	User	Value	Reason
Mar-04-2021 09:02:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:20:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-04-2021 09:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Feb-11-2021 17:20:53 (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-04-2021 09:02:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:20:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
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Form Version: 22-Apr-2020 21:03

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Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

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Generated By: (b) (4)

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

*Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Mar-04-2021 13:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 09:02:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 09:02:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 10:53:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLINQUERY: Query response notes meds were given for COVID treatment. However, medications should only be reported on this CRF if they are PROHIBITED. As these medications do not meet the definition of prohibited, please verify they were entered in error
Feb-26-2021 16:23:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Medication given during COVID treatment and recorded
Feb-26-2021 15:06:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Dexamethason is reported as a Prohibited Medication. As this

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
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Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

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				corticosteroid was taken after Visit 3, please verify it is not a prohibited medication per section 6.5.1 of the protocol. Therefore, please verify it was entered in error.
Feb-11-2021 17:20:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dexamethasone	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Mar-04-2021 09:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:20:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 6	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Mar-04-2021 09:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-11-2021 17:20:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
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Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1114

Site Name: (1114) Alliance for Multispecialty Research Inc

Subject No: 11141075

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Mar-04-2021 09:02:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 17:20:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Mar-04-2021 09:02:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 17:20:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Mar-04-2021 09:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 17:20:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/6/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 09:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Feb-11-2021 17:20:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-26-2021 15:45:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/28/2021	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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

Date	Location	User	Value	Reason
Feb-26-2021 16:58:33 (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	Transcription Error
Feb-26-2021 15:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-26-2021 15:45:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-26-2021 15:45:16 (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 and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

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

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-26-2021 15:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/1/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-26-2021 15:45:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1114

**Subject No:** 11141075

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-12-2020 09:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-22-2020 12:34:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-22-2020 12:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-12-2020 09:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Initial Entry
Aug-22-2020 12:34:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/21/2020	Initial Entry
Aug-22-2020 12:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/21/2020	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (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:** 1114

**Site Name:** (1114) Alliance for Multispecialty Research Inc

**Subject No:** 11141075

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:58

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Oct-21-2020 09:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae3d52\Final\Final On: 01-Apr-2021 04:31 (GMT)