

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/1/2020
----	--------------	---

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12291083]
2.	Birth Date:	UNK/UNK/1965
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Oct/1/2020
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: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	UNK/UNK/1997
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Human Immunoviral Infection]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[obesity]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Menopause]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is known to be HIV POSITIVE
----	---	---

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Lancet Laboratories Netcare Garden City Mayfair]
3.	Collection Date:	Aug/4/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[2124]
	Test:	HIV RNA (Ultrasensitive)
	Result:	[<50]
	LNMT	Low [28] High [58] Unit /mL

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Lancet Laboratories]
3.	Collection Date:	Aug/4/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[4722]
	Test:	CD4_PX4722
	Result:	[0.500]
	LNMT	Low [0.500] High [2.010] Unit 10^3/mm3

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/1/2020
2.	Weight:	[122.6]
3.	Unit:	kg
4.	Height:	[155.0]
5.	Unit:	cm
6.	Body Mass Index:	[51.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/1/2020
2.	Randomization Number:	[102631]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/1/2020
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	[BM9D7Z]
-----	-----------	----------

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/1/2020
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	[BM9D7N]
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[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:	Oct/1/2020 14:05
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/22/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM9DMR]
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[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:	Oct/22/2020 11:42
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (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: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LAB CHEMISTRY

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Lab Chemistry Details

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

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ HIV RNA (Ultrasensitive)	
	Result:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LABORATORY DATA - HEMATOLOGY

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Laboratory Data Hematology

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

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ CD4_PX4722	
	Result:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/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	[BM9J5D]
5.b	Sample ID	[BRSF81]
5.c	Sample ID	[BRSF82]

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Not Done _____ //	Comments
2.	Erroneous Visit	Not Done _____	Comments

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Lab Chemistry Details

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

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	Not Done _____ HIV RNA (Ultrasensitive)	
	Result:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Laboratory Data Hematology

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

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	Not Done _____ CD4_PX4722	
	Result:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ []
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Not Done _____ //	Comments
2.	Erroneous Visit	Not Done _____	Comments

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ []
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Lab Chemistry Details

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

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	Not Done _____ HIV RNA (Ultrasensitive)	
	Result:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Laboratory Data Hematology

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

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	Not Done _____ CD4_PX4722	
	Result:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Not Done _____ //	Comments
2.	Erroneous Visit	Not Done _____	Comments

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ []
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Lab Chemistry Details

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

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	Not Done _____ HIV RNA (Ultrasensitive)	
	Result:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Laboratory Data Hematology

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

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	Not Done _____ CD4_PX4722	
	Result:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Dec/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/17/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Dec/17/2020

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Dec/17/2020
2.	Date of First Symptom Started:	Dec/10/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/23/2020

Symptoms

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

Symptoms - Other

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Dec/17/2020

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a	Symptoms - Other Text:	[New or Increased Nasal Congestion]
5.b	Symptoms - Other Text:	[Nasal Discharge]
5.c	Symptoms - Other Text:	[New or Increased Sputum Production]
5.d	Symptoms - Other Text:	[New or Increased Wheezing]

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Dec/17/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Dec/17/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Dec/17/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[CLIA - certified Mullah Medical Laboratory]

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Dec/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Site collected the swab at site.]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	Not Applicable	Comments
		[]	

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Dec/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/17/2020
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	[BM9J9F]
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Dec/17/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1. DELETED	HOSPITALIZATION STATUS	HOSPITAL	Dec/28/2020	NO Discharge Date : Jan/5/2021	Repeating Pages

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS
Dec/17/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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

Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Dec/28/2020
4.	Ongoing?	NO Discharge Date: Jan/5/2021

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Dec/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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[Form Comments](#)

[eCRF Audit Trail History](#)

Respiratory Treatment

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Dec/17/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Illness Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE
Dec/17/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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[eCRF Audit Trail History](#)

Illness Details

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Dec/17/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Lab Chemistry Details

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

Lab Result

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Dec/17/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Dec/17/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.d	Sponsor ID:	Not Done _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Done _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Dec/17/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Dec/17/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Laboratory Data Hematology

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

Lab Result

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Dec/17/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Dec/17/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.d	Sponsor ID:	Not Done _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Done _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
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Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Dec/17/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.h	Sponsor ID:	Not Done _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments
5.i	Sponsor ID:	Not Done _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
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Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 15-Sep-2020 21:52

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Date:	Vital Signs Details			Form Instance
1.	Dec/17/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	135	90	

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Dec-2020 02:25

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Date:	Vital Signs Details			Form Instance
2.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	Not Applicable	Not Applicable	

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Dec/17/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Vital Signs

1.	Date:	Dec/17/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[135]
	Diastolic:	[90]
	Respiratory Rate in respirations/minute:	[20]
	Heart Rate in beats/minute:	[83]

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Dec/17/2020

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 15-Sep-2020 21:54

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Date:	Vital Signs Details		Form Instance
1.	Dec/17/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	95.0	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Dec/17/2020

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Vital Signs

1.	Date:	Dec/17/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[95.0]

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS
Dec/17/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Oxygenation Parameters

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Dec/17/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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Concomitant Medications

1.	What is the medication identifier?	Not Done _____ []	Comments
2.	Category:	Not Done _____	Comments
3.	Concomitant Medications Pre-specified:	Not Done _____	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Done _____ []	Comments
5.	Start Date:	Not Done _____ //	Comments
6.	Ongoing?	Not Done _____	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Dec/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Imaging

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Jan/02/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Date of Visit

1.	Date of Visit	Jan/2/2021
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 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Jan/02/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Signs and Symptoms

1.	Date of Assessment:	Jan/2/2021
2.	Date of First Symptom Started:	Dec/31/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Jan/5/2021

Symptoms

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

Symptoms - Other

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Jan/02/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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5.	Symptoms - Other Text:	[]
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Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jan/2/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Jan/02/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

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Generated By: (b) (4)

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Microbiology Specimen

1.	Actual Date of Collection:	Jan/2/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	POSITIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[CLIA - certified Chris Hani Baragwanath Laboratory]

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Jan/02/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Test done at the hospital]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Jan/02/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[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:	[Test done at the hospital]

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 **Form:** HEALTH CARE UTILIZATION
Jan/02/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1229**Site Name:** (1229) Newton Clinical Resarch**Subject No:** 12291083**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	YES Has the subject been in intensive care due to potential COVID-19 illness? YES
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Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Jan/1/2021	NO Discharge Date: Jan/5/2021	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS
Jan/02/2021

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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[Form Audit Trail](#)

Hospitalization Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Jan/02/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Respiratory Treatment

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Jan/02/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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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: [Covid19 Pneumonia] Date of Diagnosis: Jan/2/2021
3.	Toxicity Grade:	5

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE
Jan/02/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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[eCRF Audit Trail History](#)

Illness Details

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

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Unknown	Unknown	Unknown	Unknown	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Unknown	Unknown	Unknown	
					Unknown	Unknown	Unknown	
					Unknown	Unknown	Unknown	
					Unknown	Unknown	Unknown	
					Unknown	Unknown	Unknown	
					Unknown	Unknown	Unknown	
					Unknown	Unknown	Unknown	

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/02/2021

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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[eCRF Audit Trail History](#)

Lab Chemistry Details

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

Lab Result

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/02/2021

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/02/2021

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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

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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/02/2021

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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

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Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result :	
1.	Unknown	Unknown	Unknown	Unknown	Unknown	Unkno wn	Unkno wn	Repeating Pages
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	

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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/02/2021

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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Laboratory Data Hematology

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

Lab Result

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

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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/02/2021

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b	Sponsor ID:	Unknown _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Unknown _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/02/2021

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.d	Sponsor ID:	Unknown _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Unknown _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/02/2021

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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

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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/02/2021

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.h	Sponsor ID:	Unknown _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments
5.i	Sponsor ID:	Unknown _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/02/2021

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 15-Sep-2020 21:52

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Date:	Vital Signs Details			Form Instance
1.	Unknown	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Unknown	Unknown	Unknown	

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: VITAL SIGNS - COVID
Jan/02/2021

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Vital Signs

1.	Date:	Unknown _____ //	Comments
----	-------	------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Unknown _____ 1	
	Systolic:	Unknown _____ []	Comments
	Diastolic:	Unknown _____ []	Comments
	Respiratory Rate in respirations/minute:	Unknown _____ []	Comments
	Heart Rate in beats/minute:	Unknown _____ []	Comments

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Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 15-Sep-2020 21:54

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Date:	Vital Signs Details		Form Instance
1.	Unknown	Record Identifier:	Oxygen Saturation	Repeating Pages
		Unknown	Unknown	

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Jan/02/2021

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Vital Signs

1.	Date:	Unknown _____ //	Comments
----	-------	------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Unknown _____ 1	
	SPO2 Pulse Oximetry %	Unknown _____ []	Comments

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Unknown	Unknown	Unknown	Repeating Pages

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS
Jan/02/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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[Form Comments](#)

[eCRF Audit Trail History](#)

Oxygenation Parameters

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

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Jan/02/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Concomitant Medications

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Unknown	Unknown	Unknown	Unknown	Repeating Pages

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** IMAGING
Jan/02/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Imaging

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

Header Text: C4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: C4591001

Visit: POT_COVID_CONVA - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
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Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Unplanned Assessments

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

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/20/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 28-Mar-2021 02:28

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Vital Signs

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

Vital Signs Details

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

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

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: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Lab Urinalysis

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

Lab Result

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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?	

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Contact Outcome

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

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

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

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Jan/5/2021
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	DEATH
4.	Specify Status:	[]

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Not Done _____ //	Comments
2.	Erroneous Visit	Not Done _____	Comments

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

			Comments
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Not Done	

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Covid 19 Pneumonia	Jan/1/2021 UNK:UNK	NO End Date Time: Jan/5/2021 03:00	Repeating Pages
2.	ADVERSE EVENT	2	Diabetes Mellitus	Dec/28/2020 UNK:UNK	YES	Repeating Pages

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Covid 19 Pneumonia]
4.	Start Date Time:	Jan/1/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/5/2021 03:00
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? YES Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021007281]

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Diabetes Mellitus]
4.	Start Date Time:	Dec/28/2020 UNK:UNK
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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	NO	
12.	Was a Non-Drug Treatment given?	NO	
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED	
14.	Did the adverse event cause the subject to be discontinued from the study?	NO	
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021007281]	Comments

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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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	[]

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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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:	//

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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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?	

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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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?	

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: UNPLANNED_BOOSTER_CONTACT - **Form:** BOOSTER DOSE TRIGGER FORM
Unscheduled

Form Version: 20-Feb-2021 02:20

Form Status: Not Started

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Booster Dose Trigger Form

1.	Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit?	
----	--	--

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Not Applicable _____ //	Comments
2.	Primary Reason for Unblinding:	Not Applicable _____	Comments

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Form Comments](#)

[eCRF Audit Trail History](#)

Withdrawal Of Consent

			Comments
1.	Withdrawal of Consent Date :	Not Applicable //	

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Death Details

1.	Date of Collection / Notification of Death:	Jan/5/2021
----	---	------------

Cause of Death

2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[Covid 19 Pneumonia]

2.b	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[Diabetes Mellitus type 2]

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Jan/5/2021

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Essack Mitha	Approved	Mar-19-2021 12:54:16 (UTC+02:00) Harare, Pretoria	BOOK	Signed

Affidavit:

By my dated signature below, I, EssackMitha, 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.

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Oct-02-2020 14:54:59 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
3	Oct-02-2020 14:55:59 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
4	Feb-25-2021 15:02:16 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
4	Oct-30-2020 15:22:39 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
3	Oct-23-2020 12:52:33 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
6.a	Oct-23-2020 12:51:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
6.a	Oct-23-2020 12:51:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

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Item	Date	User	Comment
6.a	Oct-23-2020 12:51:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
4	Feb-21-2021 16:58:53 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
4	Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LAB CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LAB CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
1	Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LAB CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
2	Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LAB CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
3	Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LAB CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

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Generated By: (b) (4)

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Item	Date	User	Comment
4	Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LAB CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.a	Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LAB CHEMISTRY - Comments

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.a	Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LAB CHEMISTRY - Comments

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.a	Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
1	Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
2	Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
3	Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
4	Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
5.a	Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
5.a	Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
5.a	Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Jan-12-2021 16:21:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

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Item	Date	User	Comment
1	Jan-12-2021 16:21:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
2	Jan-12-2021 16:21:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - Comments

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Site Name: (1229) Newton Clinical Research

Subject Initials: ---

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Item	Date	User	Comment
1	Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

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Form: LAB CHEMISTRY - Comments

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Site Name: (1229) Newton Clinical Research

Subject Initials: ---

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Item	Date	User	Comment
2	Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
3	Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:55

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Subject No: 12291083

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Form: LAB CHEMISTRY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
4	Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
5.a	Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

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Item	Date	User	Comment
5.a	Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

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Item	Date	User	Comment
5.a	Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Jan-12-2021 16:21:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LABORATORY DATA - HEMATOLOGY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
1	Jan-12-2021 16:21:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:53

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Subject Initials: ---

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Item	Date	User	Comment
2	Jan-12-2021 16:21:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:53

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Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - Comments

Form Status: Data Complete, Frozen, Verified

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Header Text: C4591001

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Form Status: Data Complete, Frozen, Verified

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Header Text: C4591001

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Form Status: Data Complete, Frozen, Verified

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Form	Dec-18-2020 14:47:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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Header Text: C4591001

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Header Text: C4591001

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3	Dec-18-2020 14:47:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done
3	Dec-18-2020 14:46:40 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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5	Dec-18-2020 14:46:59 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

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6	Dec-18-2020 14:47:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done
6	Dec-18-2020 14:47:17 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

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Form	Dec-21-2020 13:16:11 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
Form	Dec-18-2020 14:49:38 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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2	Dec-18-2020 14:49:38 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable
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3	Dec-18-2020 14:49:38 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable
3	Dec-18-2020 14:49:22 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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Form Status: Data Complete, Frozen, Verified

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2.a	Jan-26-2021 14:14:40 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

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Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

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5	Dec-18-2020 15:01:29 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1	Jan-20-2021 13:20:58 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Unknown

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** IMAGING - Comments
Jan/02/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
2	Jan-20-2021 13:20:58 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** IMAGING - Comments
Jan/02/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
3	Jan-20-2021 13:20:58 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** IMAGING - Comments
Jan/02/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
4	Jan-20-2021 13:20:58 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Unknown

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-12-2021 16:28:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Potential ReVax Initial Contact

Form: DATE OF VISIT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
1	Jan-12-2021 16:28:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: Potential ReVax Initial Contact

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
2	Jan-12-2021 16:28:13 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - Comments

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Feb-24-2021 16:43:26 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: Potential ReVax Initial Contact

Form Version: 10-Dec-2020 02:25

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
1	Feb-24-2021 16:43:26 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
15	Feb-11-2021 16:01:03 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Site cannot enter on the log line.

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Jan-12-2021 16:13:23 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1	Jan-12-2021 16:13:23 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
2	Jan-12-2021 16:13:23 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Jan-12-2021 16:13:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
1	Jan-12-2021 16:13:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Essack Mitha	Approved	Mar-19-2021 12:54:16 (UTC+02:00) Harare, Pretoria	BOOK	Signed

Affidavit:

By my dated signature below, I, EssackMitha, 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	Mar-18-2021 14:43:57 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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Affidavit:

N/A

Essack Mitha	Approved	Mar-18-2021 11:52:44 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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Affidavit:

By my dated signature below, I, EssackMitha, 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.

Essack Mitha	N/A	Mar-18-2021 09:49:12 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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Affidavit:

N/A

Essack Mitha	Approved	Mar-16-2021 12:16:17 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Affidavit:

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

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

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

(b) (6)	N/A	Jan-26-2021 14:12:58 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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Affidavit:

N/A

Essack Mitha	Approved	Jan-21-2021 20:03:03 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Jan-21-2021 16:26:44 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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Affidavit:

N/A

Essack Mitha	Approved	Jan-21-2021 11:33:35 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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Affidavit:

By my dated signature below, I, EssackMitha, 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.

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

(b) (6)	N/A	Nov-20-2020 11:42:56 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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Affidavit:

N/A

Essack Mitha	Approved	Nov-17-2020 11:42:26 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-16-2020 12:50:18 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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Affidavit:

N/A

Essack Mitha	Approved	Nov-13-2020 21:33:50 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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Affidavit:

By my dated signature below, I, EssackMitha, 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-13-2020 16:50:06 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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Affidavit:

N/A

Essack Mitha	Approved	Nov-12-2020 09:52:22 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Affidavit:

By my dated signature below, I, EssackMitha, 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.

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-02-2020 14:54:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 14:54:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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I. Consent Was:

Date	Location	User	Value	Reason
Oct-02-2020 14:54:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Oct/1/2020	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Subject ID

Date	Location	User	Value	Reason
Oct-02-2020 14:53:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12291083	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-02-2020 14:53:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: UNK/UNK/1965	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-02-2020 14:54:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-02-2020 14:54:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 14:54:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRICAN AMERICA N	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-02-2020 14:54:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/1/2020	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-02-2020 14:55:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-02-2020 14:55:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-02-2020 14:55:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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I.a

Date	Location	User	Value	Reason
Oct-02-2020 14:57:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Asthma Start Date: UNK/UNK/1997 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-02-2020 14:57:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 15:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	Response satisfies query
Oct-12-2020 15:01:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject is not on corticosteroids.
Oct-09-2020 22:52:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: The subject presents at screening with ongoing asthma. Please confirm that participant is or is not currently receiving/plans to receive systemic corticosteroids with the exception of Inhaled Steroids due to this condition.
Oct-02-2020 14:57:06	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resrch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	Asthma	
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1.a Start Date:

Date	Location	User	Value	Reason
Oct-02-2020 14:57:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1997	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-02-2020 14:57:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-02-2020 15:02:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 ber: Medical Histor Human Immunovir y Term: al Infection Start Date: UNK/UNK/2008 Ongoing: YES	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

1.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-02-2020 15:02:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-10-2020 00:14:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Closed	Response satisfies query
Oct-09-2020 11:40:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data updated
Oct-05-2020 23:55:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Opened	GPD CLIN: Subject has medical history of ongoing HIV. Please confirm and update the HIV CRFs with viral load and CD4 results. Please confirm disease stability as per eligibility criteria.
Oct-02-2020 15:02:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Human Immunoviral Infection	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Oct-02-2020 15:02:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2008	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Oct-02-2020 15:02:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resrch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

I.c

Date	Location	User	Value	Reason
Oct-02-2020 15:03:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: hypertension Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-02-2020 15:03:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 15:03:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypertension	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-02-2020 15:03:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-02-2020 15:03:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-02-2020 15:03:48 (UTC+02:00) Harare,	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Pretoria			Medical History Term: Start Date: UNK/UNK/2010 Ongoing: YES	
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I.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-02-2020 15:03:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 15:03:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: obesity	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Oct-02-2020 15:03:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Oct-02-2020 15:03:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-09-2020 11:40:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Menopause Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-09-2020 11:40:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 11:40:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Menopause	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Oct-09-2020 11:40:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2016	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Oct-09-2020 11:40:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Date	Location	User	Value	Reason
Oct-09-2020 11:40:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is known to be HIV POS ITIVE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-09-2020 11:44:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-25-2020 13:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-23-2020 11:15:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-23-2020 11:15:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lancet Laboratories Netcare Garden City Mayfair	Changed Information
Oct-22-2020 15:50:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: A carriage is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Oct-09-2020 11:44:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lancet Laboratories Garden City	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-09-2020 11:44:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

4. Specimen Type:

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: LAB CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Oct-09-2020 11:44:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 11:35:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined 2124 Identifier: Test:: HIV RNA (Ultra sensitive) Result:: <50 Lab Normal Range: Low 28 High 58 Unit /mL	Transcription Error
Oct-09-2020 11:44:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 2124 Identifier: Test:: HIV RNA (Ultra sensitive) Result:: 50 Lab Normal Range: Low 28 High 58 Unit /mL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 11:44:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2124	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a Test:

Date	Location	User	Value	Reason
Oct-09-2020 11:44:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HIV RNA (Ultrasensitive)	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-16-2020 19:48:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkoyd (b) (4)	Query 1: Closed	Response satisfies query
Oct-16-2020 11:35:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-16-2020 11:35:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <50	Transcription Error
Oct-13-2020 12:55:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkoyd (b) (4)	Query 1: Reissued:Opened	GPD Clin: can you please update information on HOV RNA page accordingly? Thanks
Oct-13-2020 11:30:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	viral load <50
Oct-09-2020 22:13:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkoyd (b) (4)	Query 1: Opened	GPD Clin: Per protocol sec 10.8 viral load within 6 months before enrollment should be confirmatory for STABLE HIV disease (<50copies/ml). Please confirm RNA result, else document deviation on I/E CRF and report deviation as applicable.
Oct-09-2020 11:44:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 50	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

5.a LNMT

Date	Location	User	Value	Reason
Oct-09-2020 11:44:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 28 <i>High</i> 58 Unit /mL	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-09-2020 11:45:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-16-2020 23:00:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-16-2020 14:58:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lancet Laboratories	Transcription Error
Nov-16-2020 14:56:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Nov-16-2020 14:56:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lancet Laboratories at Garden city	Changed Information
Nov-15-2020 17:33:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM1: A carriage return is still being identified. Please click into the enterable page and press delete and backspace multiple times to remove the characters.
Nov-11-2020 22:37:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-11-2020 09:18:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Nov-11-2020 09:18:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lancet Laboratories Garden City	Changed Information
Nov-11-2020 06:55:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: A carriage return is identified, please do not press enter key or extra space in order to avoid the error just retype the lab name again. Thank you.
Oct-25-2020 12:44:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-23-2020 11:15:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Lancet Laboratories Garden City
Oct-22-2020 15:50:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: A carriage is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Oct-09-2020 11:45:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lancet Laboratories Garden City	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-09-2020 11:45:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-09-2020 11:45:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a

Date	Location	User	Value	Reason
Nov-16-2020 12:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 4722 Test:: CD4_PX47 22 Result:: 0.500 Lab Normal Range: <i>Low</i> 0.500 <i>High</i> 2.010 Unit 10^3/mm 3	Changed Information
Nov-13-2020 16:50:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 4722 Test:: CD4_PX47 22 Result:: 0.500 Lab Normal Range: <i>Low</i> 500 <i>High</i> 2010 Unit 10^3/mm 3	Transcription Error
Oct-09-2020 11:45:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 4722 Test:: CD4_PX47 22 Result:: 500	Initial Entry

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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Lab Normal Range: <i>Low</i> 500 <i>High</i> 2010 Unit 10 ³ /mm 3	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 11:45:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4722	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-09-2020 11:45:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CD4_PX4722	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-16-2020 23:01:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 12:50:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data updated
Nov-15-2020 07:49:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Please enter the LNMT Low (0.500) and LNMT High (2.010), after dividing the numbers provided (LNMT Low and LNMT High) by 1000 to allow using the Unit provided

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Header Text: C4591001**Visit:** V1_DAY1_VAX1_L**Form:** LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1229**Site Name:** (1229) Newton Clinical Research**Subject No:** 12291083**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54

				“10 ³ /mm ³ ” equivalent to “x1000/mm ³ ”
Nov-13-2020 16:50:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-13-2020 16:50:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.500	Transcription Error
Nov-13-2020 04:46:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please enter the CD4 absolute values only, LNMT Low and LNMT High, after dividing the number by 1000 to allow using the Unit provided “10 ³ /mm ³ ” equivalent to “1000/mm ³ ”
Oct-09-2020 11:45:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 500	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-16-2020 12:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.500 <i>High</i> 2.010 Unit 10 ³ /mm ³	Changed Information
Oct-09-2020 11:45:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 500 <i>High</i> 2010	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Unit	
			10 ³ /mm ³	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date:

Date	Location	User	Value	Reason
Oct-02-2020 15:04:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/1/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-02-2020 15:04:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 122.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-02-2020 15:04:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-02-2020 15:04:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 155.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-02-2020 15:04:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-02-2020 15:04:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 51.0	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

7.a

Date	Location	User	Value	Reason
Oct-02-2020 15:04:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.5 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-02-2020 15:04:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-02-2020 15:04:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-02-2020 15:04:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-02-2020 15:04:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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3. Collection Date:

Date	Location	User	Value	Reason
Oct-02-2020 14:55:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-02-2020 14:55:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier: Test:: Choriogonadotropi n Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-02-2020 14:55:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-02-2020 14:55:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-13-2020 01:24:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-09-2020 11:39:57 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject is menopausal.

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Pretoria		(b) (4), (b) (6)		
Oct-07-2020 20:40:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify why pregnancy test was not done as there is no corresponding med history showing subject is not of child bearing potential.
Oct-02-2020 14:55:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-02-2020 15:05:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-02-2020 15:05:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 102631	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Oct-02-2020 17:43:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-02-2020 17:43:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-02-2020 17:44:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-02-2020 17:43:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-02-2020 17:43:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-02-2020 17:44:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9D7Z	Initial Entry

5.a Sample ID

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (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: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Oct-02-2020 17:44:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM9D7Z	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Oct-02-2020 17:44:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-02-2020 17:44:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-02-2020 17:44:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-02-2020 17:44:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-02-2020 17:44:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-02-2020 17:44:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9D7N	Initial Entry

5.a Sample ID

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (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: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Oct-02-2020 17:44:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM9D7N	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-02-2020 15:09:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-02-2020 15:09:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-02-2020 15:09:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 09:11:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-15-2020 16:03:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data is recorded by subject so i assume it to be correct. Subject has been retrained on correct technique of recording temperature.
Oct-15-2020 15:10:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per eDiary records, e-Diary Temperature value(s) recorded is < 94 F (34.4 C). Please confirm if the thermometer recording from

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

				subject or the entry is appropriate. Thanks.
Oct-02-2020 15:09:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/1/2020 14:05	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-02-2020 15:09:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-02-2020 15:09:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-02-2020 15:09:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-02-2020 15:09:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Oct-02-2020 15:09:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-02-2020 15:09:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DIAR Y COLLECTED FOR THIS SUBJE CT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-31-2020 10:14:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 15:23:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data updated
Oct-28-2020 12:59:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Vaccination Symptoms Diary - Symptom Resolved Date form' at this visit. Thank you.
Oct-23-2020 12:50:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/22/2020	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FE VE R Were fever or systemic sympt oms present on the last day t he Subject Diary was comple ted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FAT IG UE	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.d

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH ILLS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MITING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.e Symptom:

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: DIA RR HE A Were fever or systemic sym ptoms present on the last da y the Subject Diary was co mpleted?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENE ED MUSC LE PAIN Were fever or systemi NO c symptoms present o n the last day the Subj ect Diary was complet ed?:	Initial Entry
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2.g Symptom:

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENE ED JOIN T PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.h Symptom:

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOINT PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-25-2021 15:06:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-25-2021 15:02:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-25-2021 15:02:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
Feb-25-2021 15:02:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 10:03:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Data does not match source
Oct-30-2020 15:22:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction NO s present on the last day the Subject Diary was complete d?:	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 15:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date:

Date	Location	User	Value	Reason
Oct-23-2020 12:51:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/22/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-23-2020 12:51:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.9 Temperature Unit: C Temperature Locat ORAL CAVI ion:: TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-23-2020 12:51:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-23-2020 12:51:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-23-2020 12:51:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Oct-23-2020 12:51:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-23-2020 12:52:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-23-2020 12:51:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-23-2020 12:52:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-23-2020 12:51:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-23-2020 12:52:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-23-2020 12:52:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-23-2020 12:52:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-23-2020 12:51:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of collection is reported, but result is missing. Please review and update as appropriate.
Oct-23-2020 12:51:42 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/22/2020	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Pretoria		(b) (4), (b) (6)	
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4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-23-2020 12:52:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-23-2020 12:51:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-23-2020 12:52:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-23-2020 12:51:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-23-2020 12:51:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-23-2020 12:51:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Oct-23-2020 12:51:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-23-2020 12:51:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-23-2020 12:51:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (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: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 17:10:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-22-2020 17:10:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-22-2020 17:10:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 17:10:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-22-2020 17:10:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 17:10:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9DMR	Initial Entry

5.a Sample ID

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (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: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Oct-22-2020 17:10:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM9DMR	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-23-2020 12:53:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-23-2020 12:53:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-23-2020 12:53:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-23-2020 12:53:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/22/2020 11:42	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-23-2020 12:53:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-23-2020 12:53:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

7. Route:

Date	Location	User	Value	Reason
Oct-23-2020 12:53:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-23-2020 12:53:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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
Oct-23-2020 12:53:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-20-2020 11:42:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nov/20/2020	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> FE VE R Were fever or systemic sympt oms present on the last day th e Subject Diary was complete d?: NO	Initial Entry
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> FE VE R Were fever or systemic sympt oms present on the last day th e Subject Diary was complete d?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.b

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT IG UE Were fever or systemic sympt oms present on the last day t he Subject Diary was comple ted?:	Initial Entry
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FAT IG UE Were fever or systemic sympt oms present on the last day t he Subject Diary was comple ted?:	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEA DAC HE	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry HEA DAC HE

2.c Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry CH ILL S
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom::	Initial Entry CH ILL S

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.e Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symp NO toms present on the last day the Subject Diary was compl eted?:	Initial Entry
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?:	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.f Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSEN ED MUSC LE PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSEN ED MUSC LE PAIN Were fever or systemic symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.g Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.h Symptom:

Date	Location	User	Value	Reason
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOINT PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-21-2021 16:59:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
Feb-21-2021 16:58:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS	Initial Entry

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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			Were injection site reactions present on the last day the S subject Diary was completed? :	
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the S subject Diary was completed? :	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the S subject Diary was completed ?:	Initial Entry
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-20-2020 11:43:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-20-2020 11:43:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:50:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-20-2020 11:46:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:50:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Nov-20-2020 11:46:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lancet Laboratories	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-25-2020 11:50:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:50:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-24-2020 10:50:40	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LAB CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)		
Nov-24-2020 09:56:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	Per protocol, record HIV viral load and CD4 count results from the most recent test performed since Visit 1 (if any). Please remove if the entered results are duplicate of the data already entered at visit 1 and mark form level comment as NOT APPLICABLE.
Nov-23-2020 07:58:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-20-2020 15:58:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Collection date is within 6 months of DOV
Nov-20-2020 11:46:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Collection Date is more than 6 months before DOV or is not after previous HIV RNA Collection Date. Please review and update as appropriate.
Nov-20-2020 11:46:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:50:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-20-2020 11:46:34	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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Header Text: C4591001

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Site Name: (1229) Newton Clinical Resarch

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

(UTC+02:00) Harare, Pretoria		(autocalc)	BLOOD	
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5.a

Date	Location	User	Value	Reason
Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: HIV RNA (Ultra sensitive) Result:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
Nov-24-2020 10:51:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: HIV RNA (Ultra sensitive) Result:: Lab Normal Range: Unit	Changed Information
Nov-20-2020 11:46:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 2124 Test:: HIV RNA (Ultra sensitive) Result:: <50 Lab Normal Range: Low 0 High 1000 Unit /mL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-24-2020 11:00:05 (UTC+02:00) Harare,	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LAB CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

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Pretoria				
Nov-24-2020 10:51:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-20-2020 11:46:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2124	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-20-2020 11:46:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HIV RNA (Ultrasensitive)	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:51:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Nov-20-2020 11:46:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <50	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-24-2020 11:00:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:51:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unit	Changed Information
Nov-20-2020 11:46:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low 0	Initial Entry

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

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			<i>High</i> 1000	
			Unit /mL	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:47:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Nov-20-2020 11:47:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:46:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-20-2020 11:47:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lancet Laboratories	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-25-2020 13:05:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed data has been updated
Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:47:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1229**Site Name:** (1229) Newton Clinical Resarch**Subject No:** 12291083**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54

Nov-24-2020 10:47:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-24-2020 09:56:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	Per protocol, record HIV viral load and CD4 count results from the most recent test performed since Visit 1 (if any). Please remove if the entered results are duplicate of the data already entered at visit 1 and mark form level comment as NOT APPLICABLE.
Nov-23-2020 06:36:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-20-2020 16:08:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Collection date is within 6 months of DOV
Nov-20-2020 11:47:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Collection Date is more than 6 months before DOV or is not after previous HIV RNA Collection Date. Please review and update as appropriate.
Nov-20-2020 11:47:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:47:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Nov-20-2020 11:47:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry
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5.a

Date	Location	User	Value	Reason
Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: CD4_PX47 22 Result:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
Nov-24-2020 10:47:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: CD4_PX47 22 Result:: Lab Normal Range: Unit	Transcription Error
Nov-20-2020 11:47:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 4722 Test:: CD4_PX47 22 Result:: 0.500 Lab Normal Range: Low 0.500 High 2.010 Unit 10^3/mm 3	Initial Entry

5.a Sponsor ID:

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:47:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Nov-20-2020 11:47:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4722	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-20-2020 11:47:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CD4_PX4722	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:47:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Nov-20-2020 11:47:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.500	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-24-2020 11:02:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 10:47:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unit	Transcription Error

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Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Nov-20-2020 11:47:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.500 <i>High</i> 2.010 <i>Unit</i> 10 ³ /mm ³	Initial Entry
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (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: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Nov-20-2020 16:55:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-20-2020 16:55:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-20-2020 16:56:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-20-2020 16:55:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-20-2020 16:55:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-20-2020 16:56:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9J5D	Initial Entry

5.a Sample ID

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (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: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Nov-20-2020 16:56:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM9J5D	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-20-2020 16:56:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRSF81	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-20-2020 16:56:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSF81	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-20-2020 16:56:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRSF82	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-20-2020 16:56:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSF82	Initial Entry

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Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-12-2021 16:21:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Jan-12-2021 16:21:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Lab Normal Range: Not Done	Initial Entry

5.a Sponsor ID:

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Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-12-2021 16:21:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Header Text: C4591001

Visit: V4_MONTH6_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-12-2021 16:21:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-12-2021 16:21:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-12-2021 16:21:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-12-2021 16:21:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_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: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Jan-12-2021 16:22:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 16:22:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-12-2021 16:22:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	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-12-2021 16:22:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-12-2021 16:22:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Jan-12-2021 16:22:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: C4591001

Visit: V5_MONTH12_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Jan-12-2021 16:22:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 16:22:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-12-2021 16:22:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	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-12-2021 16:22:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-12-2021 16:23:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-12-2021 16:23:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Lab Normal Range: Not Done	Initial Entry

5.a Sponsor ID:

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Jan-12-2021 16:23:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-12-2021 16:23:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-12-2021 16:23:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-12-2021 16:23:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-12-2021 16:23:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-12-2021 16:23:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-12-2021 16:25:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Jan-12-2021 16:25:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: C4591001

Visit: V6_MONTH24_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Jan-12-2021 16:26:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 16:26:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-12-2021 16:26:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	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-12-2021 16:26:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-12-2021 16:26:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-12-2021 16:26:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-12-2021 16:26:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-12-2021 16:26:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-12-2021 16:26:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Lab Normal Range: Not Done	Initial Entry

5.a Sponsor ID:

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form: LAB CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Jan-12-2021 16:26:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-12-2021 16:26:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-12-2021 16:26:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-12-2021 16:26:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-12-2021 16:27:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-12-2021 16:27:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-12-2021 16:27:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-12-2021 16:27:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-12-2021 16:27:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form: LABORATORY DATA - HEMATOLOGY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-12-2021 16:27:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-12-2021 16:27:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-12-2021 16:27:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-12-2021 16:27:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Dec/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-18-2020 14:43:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Dec-18-2020 14:40:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-18-2020 14:38:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-18-2020 12:35:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-17-2020 12:49:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-17-2020 12:49:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Dec/17/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

				Nasal Swab are missing. Please review and update as appropriate.
Dec-17-2020 12:49:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-17-2020 12:49:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Assessment:

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/10/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 14:30:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Jan-21-2021 16:26:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Jan-21-2021 16:26:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Dec/23/2020	New Information
Jan-21-2021 04:58:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	DM: Next visit should be entered only if all the symptoms at this visit resolved. If resolved, please review and update the date of last symptom resolved as appropriate. If not, please move details from next visit into this visit. Thank you.

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Jan-19-2021 22:44:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Closed	Response satisfies query
Jan-19-2021 22:43:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Jan-18-2021 14:24:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Subject died due to the symptoms stated. No stop date of the symptoms were noted.
Jan-18-2021 14:24:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject died due to the symptoms stated. No stop date of the symptoms were noted.
Jan-15-2021 23:22:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-15-2021 23:22:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Opened	Clin: It was stated in the SAE report #2021007281 that the subject experienced COVID-19 PNEUMONIA on 01Jan2021 and died on 05Jan2021. Please review and update the Date of Last Symptom Resolved
Jan-15-2021 23:21:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: It was stated in the SAE report #2021007281 that the subject experienced COVID-19 PNEUMONIA on 01Jan2021. Please confirm that at least one symptom was ongoing at the time the pneumonia was diagnosed

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Jan-15-2021 23:17:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021021831 that the subject experienced COVID-19 PNEUMONIA on 01Jan2021 and died on 05Jan2021. Please review and update the Date of Last Symptom Resolved
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASE D COUGH	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Symptom Present:	
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4.b Symptoms:

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom NO Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE P AIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: YES	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

4.h

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: YES	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: YES	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-17-2020 12:53:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

5.a

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Dec-17-2020 12:54:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - New or Increased Nasal Congestion Other:	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-17-2020 12:54:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: New or Increased Nasal Congestion	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-17-2020 12:54:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other Nasal Discharge	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-17-2020 12:54:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nasal Discharge	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-17-2020 12:55:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - New or Increased Sputum Production Other:	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-17-2020 12:55:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: New or Increased Sputum Production	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Dec-17-2020 12:55:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: New or Increased Wheezing	Initial Entry
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5.d Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-17-2020 12:55:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: New or Increased Wheezing	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
Dec/17/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Dec-21-2020 13:14:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Dec/17/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-24-2021 19:46:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query
Jan-19-2021 17:00:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data entered in Covid 19 Illness visit 2 is minimal as Site does not have any more data supplied by hospital. Data has been entered.
Jan-18-2021 19:39:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: It was stated in the SAE report #2021007281 that the subject was hospitalized for pneumonia and per AE CRF query response, subject had positive COVID-19 test result, please update as appropriate potential COVID-19 illness visit CRF forms
Dec-21-2020 13:14:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-21-2020 13:14:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-21-2020 13:14:27	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Dec/17/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	NASOPHARYNX	
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4. Assay Code and Description:

Date	Location	User	Value	Reason
Dec-21-2020 13:14:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Dec-21-2020 13:14:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-21-2020 13:14:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Dec-21-2020 13:14:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-21-2020 13:14:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CLIA - certified Mullah Medical La boratory	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Dec-18-2020 14:38:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-18-2020 14:38:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-18-2020 14:42:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-18-2020 14:41:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Dec-18-2020 14:40:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Dec-18-2020 14:40:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Dec-18-2020 14:40:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1229**Site Name:** (1229) Newton Clinical Resarch**Subject No:** 12291083**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54

Dec-18-2020 14:38:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 14:38:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-18-2020 14:38:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/17/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Dec-18-2020 14:42:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Site collected the swab at site.	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-18-2020 14:42:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: Not Applicable	Initial Entry
Dec-18-2020 14:41:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Dec-18-2020 14:38:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9J9F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-21-2020 12:52:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-18-2020 14:42:38	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	Not Applicable	
Dec-18-2020 14:41:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 14:39:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data correct as entered.
Dec-18-2020 14:38:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 7 characters in length. Please review and correct as appropriate.
Dec-18-2020 14:38:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM9J9F	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 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: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Dec-18-2020 14:39:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-18-2020 14:39:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-18-2020 14:43:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-18-2020 14:43:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-18-2020 14:43:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-18-2020 14:43:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/17/2020	Transcription Error
Dec-18-2020 14:39:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol,

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 **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: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

				please provide reason' is missing. Please review and update as appropriate.
Dec-18-2020 14:39:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-18-2020 14:43:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9J9F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 14:43:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM9J9F	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Dec/17/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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I.a

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner EMERGENC : Y ROOM Occurrence of Visit s or Contacts: NO	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Dec/17/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1229**Site Name:** (1229) Newton Clinical Resarch**Subject No:** 12291083**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitio PRIMARY CAR ner: E PHYSICIAN Occurrence of Vi NO sits or Contacts:	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Dec/17/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Occurrence of Visits or NO r Contacts:	
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Type of Practitioner: TELEPHONE C ONSULTATION Occurrence of Vi NO sits or Contacts:	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

1.f

Date	Location	User	Value	Reason
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Dec/17/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Feb-02-2021 13:11:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHE R Occurrence of Visits or Contacts: NO	Transcription Error
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-02-2021 13:11:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Number of Visits or Contacts: 1	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Feb-02-2021 15:21:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-02-2021 13:11:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Dec/17/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Feb-02-2021 13:11:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-01-2021 19:03:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Study site telehealth or in-person study site visits should not be captured as part of this CRF. Any additional healthcare services outside of the protocol study site visits are captured here. Please update.
Jan-29-2021 22:20:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Study site telehealth or in-person study site visits should not be captured as part of this CRF. Any additional healthcare services outside of the protocol study site visits are captured here. Please update.
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Site Investigator Practitioner	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 22:42:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-18-2021 14:21:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-18-2021 14:21:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject been in intensive	Transcription Error

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Dec/17/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			care due to potential COVID-19 illness? NO	
Jan-15-2021 23:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021007281 that the subject was hospitalized for pneumonia. Please review and update as appropriate potential COVID-19 illness visit CRF forms.
Dec-18-2020 14:45:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS - Audit Trail
Dec/17/2020

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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Date	Location	User	Value	Reason
Jan-20-2021 13:22:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Jan-18-2021 14:29:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History
Dec/17/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Jan-18-2021 14:29:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Jan-18-2021 14:29:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Jan-21-2021 09:56:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-20-2021 13:22:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data is not applicable
Jan-20-2021 12:39:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Admission date is 01 Dec 2020 please confirm.
Jan-18-2021 14:29:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/28/2020	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Jan-18-2021 14:29:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Discharge Date: Jan/5/2021	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Dec-18-2020 14:47:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Dec-18-2020 14:47:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-19-2021 22:43:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-18-2021 14:31:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data updated
Jan-15-2021 23:11:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021007281 that the subject was hospitalized for pneumonia. Please review and update as appropriate potential COVID-19 illness visit CRF forms.
Dec-18-2020 14:46:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
Dec/17/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Dec-18-2020 14:47:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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5. Start Date:

Date	Location	User	Value	Reason
Dec-18-2020 14:46:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Dec-18-2020 14:47:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - eCRF Audit Trail History
Dec/17/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Dec-21-2020 13:16:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry
Dec-21-2020 13:16:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-18-2020 14:48:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jan-24-2021 19:46:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 2: Closed	Response satisfies query
Jan-20-2021 13:23:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Data is correct as entered for this event.
Jan-20-2021 12:48:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	Per CRF guidelines V12 pg 153-154 was a diagnosis obtained should be "Yes" and Diagonis COVID-19 Pneumonia needs to be updated. Please update accordingly
Jan-18-2021 14:32:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Status for this report is correct as entered.
Jan-15-2021 21:28:11 (UTC+02:00)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 2: Opened	CLIQUERY: On the AE CRF, SAE is reported indicated

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Dec/17/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Harare, Pretoria				subject had Pneumonia due to COVID-19. Please update the diagnosis if available or else clarify as appropriate.
Dec-21-2020 16:47:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_CEIDT008_01
Dec-21-2020 13:16:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Dec-21-2020 13:16:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Dec-21-2020 13:16:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-21-2020 07:21:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6506528;Was a diagnosis obtained for Potential COVID-19 Illness? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Dec-18-2020 14:49:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-21-2020 16:47:11	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Closed	Auto closed by Validation Check:

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Dec/17/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

(UTC+02:00) Harare, Pretoria				VC_CEIDT008_03
Dec-21-2020 13:16:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Answered	Initial Entry
Dec-21-2020 13:16:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
Dec-21-2020 13:16:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Dec-21-2020 07:21:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Opened	DMW6506569;Toxicity Grade is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Dec-18-2020 14:49:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History
Dec/17/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Dec-18-2020 14:50:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Dec-18-2020 14:50:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Dec-18-2020 14:51:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-18-2020 14:51:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Lab Normal Range:	Not Done
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifi Not Don	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Site No: 1229

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			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.c Sponsor ID:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
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5.c LNMT

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test::: Not Done	Initial Entry

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			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.e Sponsor ID:

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Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

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Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
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Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

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Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
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5.g Not Done:

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-18-2020 14:52:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Site No: 1229

Site Name: (1229) Newton Clinical Resarch

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Subject Initials: ---

Generated By: (b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Lab Normal Range:	Not Done
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifi Not Don	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

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5.b Sponsor ID:

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5.c

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

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			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

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Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

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5.e Not Done:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.h Sponsor ID:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Test::	Not Done
			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.j Sponsor ID:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Dec-18-2020 14:53:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Audit Trail
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Form Status:

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Dec-18-2020 14:56:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
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Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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I. Date:

Date	Location	User	Value	Reason
Jan-26-2021 17:41:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-26-2021 14:13:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data cleared.
Jan-24-2021 07:59:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Check all assessments performed on 17DEC2020. If multiple values were recorded on a single day, at a minimum the most abnormal should be recorded i.e. the lowest Diastolic & Systolic Blood Pressure and the highest Heart Rate & Respiratory rate for the day
Dec-18-2020 14:56:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-18-2020 14:56:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 13 5 Diastolic:: 90 Respiratory Rate in respiratio 20 ns/minute: Heart Rate in beats/minute: 83	Initial Entry

2.a Record Identifier:

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
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Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Dec-18-2020 14:56:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Dec-18-2020 14:56:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 135	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Dec-18-2020 14:56:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 90	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Dec-18-2020 14:56:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 20	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Dec-18-2020 14:56:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 83	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Audit Trail
Dec/17/2020

Form Version: 10-Dec-2020 02:25

Form Status:

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Dec-18-2020 14:55:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
Dec/17/2020

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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I. Date:

Date	Location	User	Value	Reason
Jan-26-2021 14:14:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-26-2021 14:12:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 14:55:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-26-2021 14:14:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in respirations/minute: Not Applicable Heart Rate in beats/minute: Not Applicable	Initial Entry
Jan-26-2021 14:12:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: Diastolic:: Respiratory Rate in respirations/minute: Heart Rate in beats/minute:	Transcription Error
Dec-18-2020 14:55:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 13 5 Diastolic:: 90	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
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Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

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			Respiratory Rate in respirati ons/minute: 20	
			Heart Rate in beats/minute: 83	

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-18-2020 14:55:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-26-2021 14:14:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Jan-26-2021 14:12:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Dec-18-2020 14:55:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 135	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-26-2021 14:14:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Jan-26-2021 14:12:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Dec-18-2020 14:55:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 90	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-26-2021 14:14:40 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
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Site No: 1229

Site Name: (1229) Newton Clinical Resarch

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Subject Initials: ---

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Pretoria		(b) (4), (b) (6)		
Jan-26-2021 14:12:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 14:55:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 20	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-26-2021 14:14:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-26-2021 14:12:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-18-2020 14:55:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 83	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
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Form Status:

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Dec-18-2020 14:58:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Dec/17/2020

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date:

Date	Location	User	Value	Reason
Dec-18-2020 14:58:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-18-2020 14:58:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 95.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-18-2020 14:58:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Dec-18-2020 14:58:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 95.0	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: OXYGENATION PARAMETERS - eCRF Audit Trail History
Dec/17/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Jan-22-2021 19:20:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-18-2021 14:33:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data is not available to document.
Jan-15-2021 23:10:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021007281 that the subject was hospitalized for pneumonia. Please review and update as appropriate potential COVID-19 illness visit CRF forms.
Dec-18-2020 14:58:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Dec-18-2020 14:59:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Dec-18-2020 14:59:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Dec-18-2020 15:02:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Dec-18-2020 15:02:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Dec-18-2020 15:02:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Dec-18-2020 15:01:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Dec-18-2020 15:01:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/17/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

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Dec-18-2020 15:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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Header Text: C4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History
Dec/17/2020**Form Version:** 06-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1229**Site Name:** (1229) Newton Clinical Resarch**Subject No:** 12291083**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-19-2021 22:42:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-18-2021 14:34:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data updated
Jan-15-2021 23:15:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021007281 that the subject was hospitalized for pneumonia. Please review and update as appropriate potential COVID-19 illness visit CRF forms.
Dec-18-2020 15:03:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Dec-18-2020 15:03:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Dec-18-2020 15:03:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History
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Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Dec-18-2020 15:03:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Jan/02/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-09-2021 12:23:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-08-2021 15:58:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Subject is deceased and thus visit cannot occur.
Feb-08-2021 14:20:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ: Convalescent visit is missing and 35+ days (37) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Jan-22-2021 18:19:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-22-2021 14:37:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject's swabs were collected at the hospital and did not use study materials.
Jan-22-2021 12:40:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	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-20-2021 13:13:12 (UTC+02:00) Harare,	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Jan/02/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Pretoria				
Jan-19-2021 16:39:29 (UTC+02:00) Harare, Pretoria	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.
Jan-19-2021 16:39:29 (UTC+02:00) Harare, Pretoria	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-19-2021 16:39:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/2/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-19-2021 16:39:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

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Header Text: C4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1229**Site Name:** (1229) Newton Clinical Resarch**Subject No:** 12291083**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/2/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-24-2021 19:45:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query
Jan-22-2021 14:38:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data entered as per DM request.
Jan-21-2021 17:48:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: Given that the subject has ongoing symptoms in the COVID_A visit, please clarify the need of this separate visit. Per protocol, if the subject develops additional symptoms while symptoms from prior visit ongoing, should be added in 1st visit
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Jan/5/2021	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
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Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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4.a

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREAS ED COUGH Symptom P NO resent:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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4.c

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: CHILLS Symptom Present: NO	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom NO Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: NEW LOSS OF TAS TE OR SMELL	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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			Symptom Present:	NO
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4.f Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW LOSS OF TASTE OR SMEL L	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms NEW OR INCREASE : D SORE THROAT Symptom NO Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SORE TH ROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
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Header Text: C4591001

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Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: DIARRHEA Symptom Present: NO	Initial Entry
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4.h Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: VOMITING Symptom Present: YES	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-20-2021 13:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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Header Text: C4591001

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Jan/02/2021

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Form Status:

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Jan-19-2021 16:58:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Jan/02/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-19-2021 16:58:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/2/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-19-2021 16:58:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-19-2021 16:58:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-19-2021 16:58:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jan-19-2021 16:58:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-19-2021 16:58:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OTHER	Initial Entry

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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Jan/02/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

7. Test Result:

Date	Location	User	Value	Reason
Jan-19-2021 16:58:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: POSITIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-19-2021 16:58:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CLIA - certified Chris Hani Baragw anath Laboratory	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Jan-20-2021 13:13:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 13:13:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 13:13:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-20-2021 13:13:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Test done at the hospital	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 **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: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Jan-20-2021 13:13:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 13:13:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 13:13:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-20-2021 13:13:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Test done at the hospital	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/02/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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I.a

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIA LIST Occurrence of Visits or NO Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or YES Contacts <i>Number of Visit s or Contacts:</i> 1	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/02/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1229**Site Name:** (1229) Newton Clinical Resarch**Subject No:** 12291083**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.c

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/02/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/02/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

1.f

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHE R Occurrence of Visits or C NO ontacts:	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 13:14:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject been in intensive c are due to potential COVID-19 illn ess? YES	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS - Audit Trail
Jan/02/2021

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Jan-20-2021 13:15:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History
Jan/02/2021

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Jan-20-2021 13:15:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Jan-20-2021 13:15:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Jan-20-2021 13:15:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2021	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 13:15:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Discharge Date: Jan/5/2021	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: RESPIRATORY TREATMENT - eCRF Audit Trail History
Jan/02/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Jan-20-2021 13:15:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-20-2021 13:15:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-20-2021 13:15:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Jan-20-2021 13:15:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-20-2021 13:15:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 13:15:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: ILLNESS DETAILS - eCRF Audit Trail History
Jan/02/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-20-2021 13:17:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jan-20-2021 13:17:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Covid19 Pneumonia Date of Diagnosis: Jan/2/2021	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-20-2021 13:17:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 5	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History
Jan/02/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-20-2021 13:17:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-20-2021 13:17:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-20-2021 13:17:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-20-2021 13:17:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Lab Normal Range:	Unknown
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identif Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			ier:	n	
			Test::	Unknow	
				n	
			Result::	Unknow	
				n	
			Not Done::	Unknow	
				n	
			Lab Normal Range:	Unknow	
				n	

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Unknown Test:: Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
Jan/02/2021

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Result::	Unknow n
			Not Done::	Unknow n
			Lab Normal Range:	Unknow n

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.d

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Unknow n Test:: Unknow n Result:: Unknow n Not Done:: Unknow n Lab Normal Range: Unknow n	Initial Entry

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Generated Time (GMT): 29-Mar-2021 13:54

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

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5.d Not Done:

Date	Location	User	Value	Reason
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5.d LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Unknown Test:: Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

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			Result::	Unknow n
			Not Done::	Unknow n
			Lab Normal Range:	Unknow n

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5.e Not Done:

Date	Location	User	Value	Reason
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5.e LNMT

Date	Location	User	Value	Reason
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5.f

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.f Result:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Unknown Test:: Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

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Jan/02/2021

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Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Result::	Unknow n
			Not Done::	Unknow n
			Lab Normal Range:	Unknow n

5.g Sponsor ID:

Date	Location	User	Value	Reason
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5.g Test:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
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5.g Not Done:

Date	Location	User	Value	Reason
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5.g LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

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Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
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Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Lab Normal Range:	Unknow n	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identif Unknow	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			ier:	n	
			Test::	Unknow	
				n	
			Result::	Unknow	
				n	
			Not Done::	Unknow	
				n	
			Lab Normal Range:	Unknow	
				n	

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/02/2021 Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.c

Date	Location	User	Value	Reason
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			Result::	Unknow n
			Not Done::	Unknow n
			Lab Normal Range:	Unknow n

5.c Sponsor ID:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

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Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Unknown Test:: Unknown	Initial Entry

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			Result::	Unknow n
			Not Done::	Unknow n
			Lab Normal Range:	Unknow n

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Unknown Test:: Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/02/2021 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Result::	Unknow n
			Not Done::	Unknow n
			Lab Normal Range:	Unknow n

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.h

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Unknow n Test:: Unknow n Result:: Unknow n Not Done:: Unknow n Lab Normal Range: Unknow n	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/02/2021 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.h Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.i

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identif ier: Unknow n Test:: Unknow n	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Result::	Unknow n	
			Not Done::	Unknow n	
			Lab Normal Range:	Unknow n	

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/02/2021 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.j

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/02/2021 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Test::	Unknow n
			Result::	Unknow n
			Not Done::	Unknow n
			Lab Normal Range:	Unknow n

5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Jan-20-2021 13:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/02/2021

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date:

Date	Location	User	Value	Reason
Jan-20-2021 13:19:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-20-2021 13:19:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: Unkno wn Systolic:: Unkno wn Diastolic:: Unkno wn Respiratory Rate in respir ations/minute: Unkno wn Heart Rate in beats/minut e: Unkno wn	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-20-2021 13:19:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-20-2021 13:19:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-20-2021 13:19:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/02/2021

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Pretoria		(b) (4), (b) (6)		
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-20-2021 13:19:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-20-2021 13:19:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Jan/02/2021

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date:

Date	Location	User	Value	Reason
Jan-20-2021 13:19:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-20-2021 13:19:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: Unknown Oxygen Saturation: Unknown	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-20-2021 13:19:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-20-2021 13:19:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History
Jan/02/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Jan-20-2021 13:20:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Jan-20-2021 13:20:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Jan-20-2021 13:20:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Jan/02/2021 Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-20-2021 13:20:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-20-2021 13:20:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-20-2021 13:20:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Jan-20-2021 13:20:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-20-2021 13:20:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
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090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Jan/02/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Jan-20-2021 13:20:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unknown	Initial Entry
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Header Text: C4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History
Jan/02/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-20-2021 13:20:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-20-2021 13:20:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-20-2021 13:20:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-20-2021 13:20:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unknown	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-20-2020 11:48:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-20-2020 11:48:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-20-2020 11:48:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae306b\Final\Final On: 01-Apr-2021 04:06 (GMT)

Header Text: C4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1229**Subject No:** 12291083**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1229) Newton Clinical Resarch**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-13-2021 04:31:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-12-2021 16:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-12-2021 16:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/5/2021	New Information
Jan-11-2021 11:56:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021007281, the date of death was reported as 05Jan2021 in Safety database but missing in CRF. Please confirm correct date of death. If safety update is required, please submit a follow-up form.

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-12-2021 16:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	New Information

3. Status:

Date	Location	User	Value	Reason
Jan-12-2021 16:06:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DEATH	Initial Entry

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:** 1229**Site Name:** (1229) Newton Clinical Resarch**Subject No:** 12291083**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-25-2021 04:25:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_SV001_12
Feb-24-2021 16:42:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Visit is not possible as subject has deceased.
Feb-24-2021 15:28:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7406678;FURTHER VACCINATION CONFIRMATION CRF is completed, however date of visit is missing for REVAX_CONTACT. Please review and update as appropriate.
Jan-12-2021 16:28:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Jan-12-2021 16:28:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Date	Location	User	Value	Reason
Feb-24-2021 16:43:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1229) Newton Clinical Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-15-2021 11:52:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	new query in AE#@ was added
Feb-15-2021 11:51:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON: Diabetes Mellitus no longer listed in SDB but was added in AE CRF. per previous query response 'The Investigator's opinion is the there is no Diabetes Mellitus.Please inactivate AE#2 per query response.
Feb-11-2021 16:08:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	AER # 2021007281 data has been documented.
Feb-10-2021 06:37:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON:Diabetes Mellitus still recorded in SDB. Please confirm if follow up AEM form was submitted indicating per previous query response 'The Investigator's opinion is the there is no Diabetes Mellitus.'

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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Feb-08-2021 14:07:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Covid 19 Pneumonia	Transcription Error
Feb-05-2021 13:48:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Site will submit on Monday
Feb-04-2021 21:54:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON: Please submit a new SAE form to clarify per previous query response 'The Investigator's opinion is the there is no Diabetes Mellitus.'
Jan-29-2021 17:33:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Closed	Response satisfies query
Jan-26-2021 14:00:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Updated Follow up Report has been sent to ICON.
Jan-24-2021 17:46:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Reissued:Opened	Response does not satisfy query.
Jan-21-2021 17:45:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 4: Closed	Response satisfies query
Jan-20-2021 13:23:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Data is not available to site.
Jan-20-2021 11:50:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	Pending SDB update
Jan-19-2021 23:53:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 5: Opened	CLINICAL_ Per report, the subject died because of Covid Pneumonia. However, information on clinical presentation, workup (relevant lab result, including imaging) and treatment are not described. Kindly provide further details in a FU report. Thank you

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Site No: 1229

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Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Jan-19-2021 16:59:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Data entered in Covid 19 Illness visit 2 is minimal as Site does not have any more data supplied by hospital. Data has been entered.
Jan-19-2021 16:37:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Documents were faxed to zaf.aereporting@pfizer.com
Jan-19-2021 12:10:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON 2: Diabetes mellitus was reported in Safety database. Please submit a follow up AEM form to clarify per previous query response 'The Investigar's opinion is the there is no Diabetes Mellitus.'
Jan-18-2021 19:37:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 4: Reissued:Opened	CLIQUEY: thank you for your response. Per protocol, all COVID-19 related illness should be captured in potential COVID-19 illness visit CRFs. please clarify.
Jan-18-2021 14:18:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Subject did have a positive SARS-COV-2 PCR results on 02/Jan/2021.
Jan-18-2021 14:16:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Thank you for the mail. In the opinion of the Investigator, the high Glucose level is associated with the Covid 19 infection. The Investigar's opinion is the there is no Diabetes Mellitus.
Jan-17-2021 13:01:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	SAE RECON 1:In safety database, Diabetes mellitus and Covid pneumonia were reported. Please confirm event seriousness and update AE CRF accordingly.

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Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1229**Subject No:** 12291083**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1229) Newton Clinical Resarch**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54

Jan-15-2021 21:32:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 4: Opened	CLIQUEY: please clarify if the subject had a positive COVID-19 test result as indicated in the AE term. All COVID-19 related illness details should be captured in COVID-19 illness visit CRFs. Please clarify.
Jan-15-2021 15:28:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Jan-15-2021 15:28:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Covid 19 Positive Pneumonia	Transcription Error
Jan-15-2021 02:10:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Thanks for confirming. Please make every effort possible to obtain further information on clinical course/hospital stay and respond to the query once additional it is available.
Jan-13-2021 21:56:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	ClinQuery: Please clarify reason for death as term of "COVID Positive" does not = death.
Jan-13-2021 16:56:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Form to be completed by SI on 14 Jan 2021, and will be sent.
Jan-13-2021 13:56:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2021007281,the term was reported as 'Diabetes mellitus' in Safety database while recorded as 'Covid 19 Positive' in AE CRF. Please confirm correct term.If safety update is required, please submit a follow-up form
Jan-12-2021 16:11:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

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Jan-12-2021 16:11:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Covid 19 Positive	Changed Information
Jan-10-2021 18:41:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Per report, medical records are pending. Kindly provide further information on clinical course/hospital stay in a FU form. Please make every effort to obtain this further details. Thank you.
Jan-06-2021 15:58:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-06-2021 13:12:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No history of DM at screening.
Jan-05-2021 19:38:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify if there was a history of Diabetes Mellitus prior to signing consent, if yes- please add to the medical history form.
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetes Mellitus	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 19:10:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-11-2021 16:06:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Feb-11-2021 16:06:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2021 UNK:UNK	Transcription Error
Feb-11-2021 03:46:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2021007281 ,onset date was updated to 04Jan2021

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				in AE CRF however, recorded as 01Jan2021 in Safety database. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Feb-09-2021 15:04:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/4/2021 UNK:UNK	Transcription Error
Jan-25-2021 08:08:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	onset date updated
Jan-22-2021 20:05:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON 2: Per your query response "transcription error" however data has not been updated. Please confirm the correct onset date and update the CRF accordingly or submit a follow up SAE form with correct onset date if Safety database should be updated.
Jan-20-2021 13:54:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-20-2021 13:54:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2021 UNK:UNK	Transcription Error
Jan-20-2021 13:43:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON 1: onset date was recorded as 01Jan2021 in Safety database while updated as 01Dec2020 in AE CRF. pPlease confirm and update accordingly.
Jan-20-2021 13:24:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

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Subject No: 12291083

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

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Jan-20-2021 13:24:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/1/2020 UNK:UNK	Transcription Error
Jan-20-2021 11:54:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2021007281 ,onset date was recorded as 01Jan2021 in Safety database however, recorded as 28Dec2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.

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4. Start Date Time:

Date	Location	User	Value	Reason
Jan-05-2021 12:37:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-05-2021 12:37:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/28/2020 UNK:UNK	Transcription Error
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Diabetes Mellitus Start Date 28/Dec /2021, is a future date relative to when it was entered on 05/Jan/2021. Please correct.
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/28/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-05-2021 12:37:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Diabetes Mellitus End Date & Time 05/Jan/2021 03:00 is before the Start Date & Time 28/Dec/2021 UNK:UNK.
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/5/2021 03:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Jan-05-2021 22:10:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-05-2021 19:41:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: AE is recorded as FATAL, however, tox = 4. Please clarify. IF event is fatal then tox must = 5. Please correct appropriately.
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-08-2021 13:56:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-06-2021 16:35:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	On admission diagnoses was Diabetes Mellitus, patient has now died hence AE has been entered as SERIOUS. Site is awaiting medical report from family to update and finalize the report.
Jan-06-2021 14:22:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:Diabetes Mellitus(Onset date:28Dec2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer

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Subject No: 12291083

Generated By: (b) (4)

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				immediately. If this event is not serious, downgrade the event on AE CRF
Jan-06-2021 05:29:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Diabetes Mellitus: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>YES</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p>	Initial Entry

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Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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			NO	
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> Unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-15-2021 19:52:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-06-2021 13:11:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	On admission patient was diagnosed with Diabetes Mellitus confirmed by family, otherwise site still awaiting medical report.
Jan-05-2021 19:42:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Outcome is reported as Fatal, Diabetes Mellitus typically does not result in death. Was death due to complications from DM? Please clarify.
Jan-05-2021 12:39:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "What was the outcome of this adverse event?" is 'Fatal' but Date of Collection / Notification of Death on the Death Details form is not completed. Please review and update as appropriate.
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATAL	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 12:40:54 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closing as FUP details are entered

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Pretoria				
Jan-12-2021 16:19:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data entered.
Jan-08-2021 15:30:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Did the adverse event cause the subject to be discontinued from the study? is marked as Yes, however, Disposition CRF is not started. Please review and update the data appropriately.
Jan-05-2021 12:37:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-08-2021 13:54:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021007281	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-12-2021 15:03:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-12-2021 11:45:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Diabetes Mellitus was an initial diagnosis upon admission.
Feb-11-2021 17:05:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls confirm this is a new diagnosis, thanks
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetes Mellitus	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/28/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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Feb-26-2021 07:28:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Feb-24-2021 12:00:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	AE was ongoing before death.
Feb-24-2021 11:56:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Feb-24-2021 11:56:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Feb-23-2021 00:28:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-21-2021 16:12:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Feb-21-2021 16:12:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/5/2021 03:00	Transcription Error
Feb-20-2021 01:44:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY: apologies, please clarify if the stop date for Diabetes Mellitus should be updated to 5/Jan/2021 03:00 for consistency with the stop of the other fatal AE of Covid 19 Pneumonia.
Feb-20-2021 01:41:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-19-2021 14:47:36	ACV0PFEINFP6000	auto query	Query 2: Answered	Transcription Error

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(UTC+02:00) Harare, Pretoria		(autoquery)		
Feb-19-2021 14:47:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/5/2021 UNK:UNK	Transcription Error
Feb-19-2021 03:57:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: for the AE of Diabetes Mellitus, please provide the stop date for this fatal event. Note: date of death provided is 5/Jan/2021.
Feb-10-2021 11:56:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 15:20:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	AE was ongoing before the patient passed away, hence we don't have a stop date.
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-10-2021 22:17:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-10-2021 13:15:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	AE is life threatening cause it led to death.

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Mar-09-2021 18:26:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: This is usually not a life threatening AE, please clarify why this is considered life threatening.
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-19-2021 20:47:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 6: Closed	Response satisfies query
Mar-19-2021 11:16:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Answered	Data changed per query
Mar-19-2021 11:16:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity?	Data changed per query

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			NO Is this serious event life threatening? YES Other medically important serious event NO	
Mar-19-2021 00:02:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	CLINQUERY: please clarify if subquestion "Is this serious event life threatening?" should be YES. Note: the toxicity grade for Diabetes Mellitus is reported as 4 (protocol 10.3.3 Life-threatening consequences; urgent intervention indicated).
Mar-18-2021 23:55:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Mar-18-2021 14:43:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Deleted	Close Auto Query
Mar-18-2021 14:43:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	data changed per query
Mar-18-2021 14:43:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death?	data changed per query

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			<p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Mar-18-2021 14:38:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	CLINQUERY: thank you for clarifying that diabetes did not result in death, however, please confirm that Is AE serious is YES and that the subquestion 'Did this serious event result in death?' for Diabetes Mellitus should be NO.
Mar-18-2021 09:49:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	For AE Diabetes Mellitus: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Mar-18-2021 09:49:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Info changed as per query. Diabetes did not result in death. Death was due to Covid Pneumonia

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Mar-18-2021 09:49:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Essack Mitha (b) (4)	Data Entry: NO	Info changed as per query. Diabetes did not result in death. Death was due to Covid Pneumonia
Mar-17-2021 17:44:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	GPD CLIN: Per safety narrative, the cause of death was reported as disease progression and COVID pneumonia while diabetes was serious due to hospitalization. Please clarify if 'Did this serious event result in death?' for Diabetes Mellitus should be NO.
Mar-17-2021 17:42:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	revised and reposted
Mar-17-2021 16:52:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 3: Opened	GPD CLIN: Per safety narrative, the cause of death was reported as disease progression and COVID pneumonia while diabetes was serious due to hospitalization. Please review and update the fatal outcome of diabetes as "No" as applicable.
Feb-19-2021 07:35:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Added back to SDB. Issue resolved
Feb-18-2021 09:43:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Pending Clinical review
Feb-17-2021 16:15:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE# 2021007281 Follow Up form has been sent to Pfizer.

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Feb-15-2021 11:54:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON:Per response in another query 'In the opinion of the Investigator, the high Glucose level is associated with the Covid 19 infection.The Investigar's opinion is the there is no Diabetes Mellitus.Please confirm if AE should be inactivated.
Feb-15-2021 11:51:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-12-2021 19:09:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Pending Clinical Review
Feb-11-2021 23:28:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	As per site confirmation, Serious Adverse Event Number is for Pfizer use only and site cannot enter data on the following field.
Feb-11-2021 16:03:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Site cannot enter data on log line #14.

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-11-2021 15:57:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	initial SAE form diagnosis was Diabetes Mellitus.
Feb-10-2021 21:02:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: SAE of Diabetes Mellitus has been removed from Safety database however reported as "serious" in AE CRF. Please confirm correct Seriousness .If safety update is required, please submit a follow-up form
Feb-10-2021 12:28:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	For AE Diabetes Mellitus: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Diabetes Mellitus: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect?	Initial Entry

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			NO	
			Did this serious event result in death?	
			YES	
			Did this serious event require or prolong hospitalization?	
			YES	
			Did this serious event result in persistent or significant disability/in capacity?	
			NO	
			Is this serious event life threatening?	
			YES	
			Other medically important serious event	
			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.

Date	Location	User	Value	Reason
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i>	Initial Entry

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			unknown	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 14:38:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-24-2021 11:57:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Feb-24-2021 11:57:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-24-2021 11:57:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NO T RESOLVED	Transcription Error
Feb-24-2021 11:56:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Diabetes Mellitus: Response to "What was the outcome of this adverse event?" is 'Fatal' but "Is the

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Header Text: C4591001

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Subject No: 12291083

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Verified

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				adverse event still ongoing?" is marked 'Yes'.
Feb-23-2021 01:31:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021007281,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as FATAL on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-19-2021 14:47:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Answer Auto Query
Feb-12-2021 19:08:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candi date	Pending Clinical Review
Feb-09-2021 15:14:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	AE was ongoing before the patient passed away, hence we don't have a stop date.
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Diabetes Mellitus: Response to "What was the outcome of this adverse event?" is 'Fatal' but "Is the adverse event still ongoing?" is marked 'Yes'.
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATAL	Initial Entry

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

Date	Location	User	Value	Reason
Mar-18-2021 14:39:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-18-2021 09:51:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Data value changed as per query
Mar-18-2021 09:51:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Essack Mitha (b) (4)	Data Entry: NO	Data value changed as per query

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Mar-17-2021 17:35:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	per safety narrative the cause of death was reported as disease progression and COVID pneumonia while diabetes was serious due to hospitalization. Please confirm that Q#14 (event cause discontinue from study) for Diabetes Mellitus should be updated to NO
Mar-17-2021 17:22:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	covered by clinical query; should be updated to no
Mar-16-2021 19:47:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Event outcome is not Fatal however "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'. Please confirm if Diabetes caused the subject to discontinue and update appropriately.
Feb-10-2021 01:15:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 15:16:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	AE1 and AE2 happened at the same time.
Feb-09-2021 15:10:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'.
Feb-09-2021 15:10:27	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	YES	
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-19-2021 07:35:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021007281	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-12-2021 16:13:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-12-2021 16:13:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

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I. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Jan-12-2021 16:13:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1229

Site Name: (1229) Newton Clinical Resarch

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Jan-05-2021 12:39:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/5/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-19-2021 11:11:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH Cause of Death: Covid 19 Pneumonia	Transcription Error
Mar-19-2021 11:11:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH Cause of Death: Covid 19 positive	Transcription Error
Feb-09-2021 15:18:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cause of Death Status: SECONDARY CAUSE OF DEATH Cause of Death: Covid 19 positive	Transcription Error
Jan-12-2021 16:15:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH Cause of Death: Covid 19 positive	Initial Entry

2.a Cause of Death Status:

Date	Location	User	Value	Reason
Mar-19-2021 11:11:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CAUSE OF DEATH	Transcription Error
Feb-09-2021 15:18:03 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SECONDARY CAUSE OF DEATH	Transcription Error

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Pretoria			H	
Jan-12-2021 16:15:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CAUSE OF DEATH	Initial Entry

2.a Cause of Death:

Date	Location	User	Value	Reason
Mar-19-2021 17:15:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Closed	Response satisfies query
Mar-19-2021 11:11:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-19-2021 11:11:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Covid 19 Pneumonia	Transcription Error
Mar-18-2021 15:53:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPD CLIN: Page is unlocked Please update. Thank you
Mar-18-2021 15:46:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Reissued:Candidate	GPD CLIN: Please unlock CRF so site can make updates. Thank you!
Mar-18-2021 09:53:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Essack Mitha (b) (4)	Query 1: Answered	I agree - will make changes as soon as page is unlocked
Mar-17-2021 16:50:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Opened	GPD CLIN: Per Argus "Cause of death was reported as disease progression and COVID pneumonia". As indicated in the safety narrative, please indicate the cause of death as COVID pneumonia only.
Jan-12-2021 16:15:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Covid 19 positive	Initial Entry

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2.b

Date	Location	User	Value	Reason
Mar-19-2021 11:10:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH Cause of Death: Diabetes Mellitus type 2	Transcription Error (DELETED)
Feb-09-2021 15:17:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH Cause of Death: Diabetes Mellitus type 2	Initial Entry

Header Text: C4591001

Visit: Disposition - Unscheduled

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Form Status: Data Complete, Frozen, Verified

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Site Name: (1229) Newton Clinical Research

Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.b Cause of Death Status:

Date	Location	User	Value	Reason
Mar-19-2021 11:10:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CAUSE OF DEATH	Transcription Error (DELETED)
Feb-10-2021 01:13:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 15:18:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data updated.
Feb-09-2021 15:17:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	There is more than one primary cause of death reported. Please update so that there is one Primary Cause of death, noting that there can be multiple Secondary Causes of death.
Feb-09-2021 15:17:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CAUSE OF DEATH	Initial Entry

2.b Cause of Death:

Date	Location	User	Value	Reason
Mar-19-2021 20:40:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Closed	Response satisfies query
Mar-19-2021 11:10:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetes Mellitus type 2	Transcription Error (DELETED)
Mar-19-2021 11:10:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-18-2021 15:54:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Page unlocked please update. Thank you

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Header Text: C4591001

Visit: Disposition - Unscheduled

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Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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Mar-18-2021 15:48:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Reissued:Candidate	GPD CLIN: Please unlock CRF so site can make updates. Thank you!
Mar-18-2021 09:53:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Essack Mitha (b) (4)	Query 1: Answered	I agree - please unfreeze page so change can be made
Mar-17-2021 16:43:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Opened	GPD CLIN: Per review of safety narrative, the cause of death was COVID pneumonia. Please review and update death CRF as applicable.
Feb-09-2021 15:17:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetes Mellitus type 2	Initial Entry

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Header Text: C4591001

Visit: Subject Status - Unscheduled

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Form Status: Data Complete, Verified

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Subject No: 12291083

Subject Initials: ---

Generated By: (b) (4)

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1. Subject Status

Date	Location	User	Value	Reason
Jan-12-2021 16:06:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Nov-20-2020 11:48:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-02-2020 15:05:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-02-2020 14:55:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jan-12-2021 16:06:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/5/2021	Initial Entry
Jan-12-2021 16:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/20/2020	New Information
Dec-21-2020 12:07:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	data updated
Dec-18-2020 15:11:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data updated.
Dec-15-2020 21:30:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on

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				10DEC2020. But there is no COVID Illness visit reported in the database. Please clarify.
Nov-20-2020 11:48:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/20/2020	Initial Entry
Oct-02-2020 15:05:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/1/2020	Initial Entry
Oct-02-2020 14:55:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/1/2020	Initial Entry

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Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1229

Subject No: 12291083

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1229) Newton Clinical Resarch

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-12-2020 09:52:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Essack Mitha (b) (4)	Data Entry: Click Here to Enable	Initial Entry