

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/30/2020
----	--------------	--

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12471121]
2.	Birth Date:	UNK/UNK/2001
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** DATE OF VISIT

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/30/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1247

**Subject No:** 12471121

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/30/2020
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:** 1247

**Subject No:** 12471121

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

Form Comments

**Medical History Details**

1.	Line/MH Number:	Not Applicable _____ []
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____ []
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** HIV STATUS

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	---	---



**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:56

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/30/2020
2.	Weight:	[88.0]
3.	Unit:	kg
4.	Height:	[183.0]
5.	Unit:	cm
6.	Body Mass Index:	[26.3]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.9]
	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:** 1247

**Subject No:** 12471121

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/30/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** RANDOMIZATION

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/30/2020
2.	Randomization Number:	[102046]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
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	[BM9CM6]
5.b	Sample ID	[BRSF21]
5.c	Sample ID	[BRSF22]

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**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
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	[BM9CLH]
-----	-----------	----------

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** VACCINATION

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/30/2020 11:24
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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[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:** 1247

**Subject No:** 12471121

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

**Form:** DATE OF VISIT

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/21/2020
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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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?	YES Ongoing? NO Stop Date: Oct/6/2020
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Oct/6/2020
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Oct/6/2020
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Oct/6/2020
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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Oct/6/2020
2.g	Symptom:	NEW OR WORSENER MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENER JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/21/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[37.2]
	Unit:	C
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/21/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BM9D1T]
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090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** VACCINATION

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**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/21/2020 10:17
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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 15-Sep-2020 21:56

**Form Status:** Not Started

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	
2.	Symptom:	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	
3.	Injection Site Location:	
4.	Injection Site Body Side:	
5.	Injection Site Reaction:	
	Were injection site reactions present on the last day the Subject Diary was completed?	

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/5/2020
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  
Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Oct/5/2020
2.	Date of First Symptom Started:	Oct/1/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/7/2020

**Symptoms**

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

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** MICROBIOLOGY SPECIMEN

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Microbiology Specimen**

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Oct/5/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[CV24081]
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090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin		
2.	Sample Type		
3.	Sample Collected?	Not Done	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Only self swab done.]	

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020**Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[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:	YES Number of Visits or Contacts: [1]
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	Not Applicable [ ]	<a href="#">Comments</a>
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO	
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**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** RESPIRATORY TREATMENT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Respiratory Treatment**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** ILLNESS DETAILS

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Illness Details**

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

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** ILLNESS DETAILS - SEVERE

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Illness Details**

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

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

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

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Lab Chemistry Details**

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

**Lab Result**

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

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

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

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

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

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

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

5 f	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		
5.g	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Creatinine_PX48	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Laboratory Data Hematology**

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

**Lab Result**

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

5 f	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Neutrophils_PX608	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		
5.g	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Eosinophils_PX609	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

5.h	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Monocytes_PX612	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		
5.i	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Basophils_PX610	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** VITAL SIGNS - COVID

**Form Version:** 15-Sep-2020 21:52

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (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:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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[Form Comments](#)

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**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** OXYGENATION PARAMETERS

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Oxygenation Parameters**

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Concomitant Medications**

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** IMAGING

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Imaging**

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

**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:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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 1 - Unscheduled Visit on  
Oct/01/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/01/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/01/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/1/2020  Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[Patient contacted 01, 02 and 05 Oct. Patient advised to do home swab 05 Oct - patient symptoms were improving and patient was not limited in her activities]



**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on  
Oct/02/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on  
Oct/02/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on  
Oct/02/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/2/2020  Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Oct/05/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Oct/05/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Unplanned Assessments**

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Oct/05/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/5/2020  Contact Outcome: VISIT ARRANGED, BUT NOT ATTENDED
3.	Comments:	[Pt. invited for consultation, pt. doesn't feel its necessary.]

**Header Text:** c4591001

**Visit:** Unplanned 4 - Unscheduled Visit on  
Oct/21/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Unplanned 4 - Unscheduled Visit on  
Oct/21/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Unplanned Assessments**

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



**Header Text:** c4591001

**Visit:** Unplanned 4 - Unscheduled Visit on  
Oct/21/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/21/2020  Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned 5 - Unscheduled Visit on  
Oct/23/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/23/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 5 - Unscheduled Visit on  
Oct/23/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned 5 - Unscheduled Visit on  
Oct/23/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/23/2020  Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on  
Oct/24/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on  
Oct/24/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on  
Oct/24/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/24/2020  Contact Outcome: VISIT NOT ARRANGED, REACTION NO LONGER PRESENT
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on  
Oct/28/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

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



**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on  
Oct/28/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on  
Oct/28/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Oct/28/2020  Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Flail Chest	Oct/30/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Motorcycle accident	Oct/30/2020 UNK:UNK	NO End Date Time:  Oct/30/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Flail Chest]
4.	Start Date Time:	Oct/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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? NO  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: [Flail chest secondary to motorcycle accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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	[2020428199]

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1247**Subject No:** 12471121**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen, Not Complete**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Category	Medication Error	Start Date	Is the medication error Still On going	Study Medication Errors Action	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**Medication Error**

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

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**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Concomitant Medications**

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

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**Concomitant Medications**

1.	What is the medication identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Dose:	Not Applicable _____ [ ]	<a href="#">Comments</a>
6.	Dose Unit:	Not Applicable _____	<a href="#">Comments</a>
7.	Dose Frequency:	Not Applicable _____	<a href="#">Comments</a>
8.	Route:	Not Applicable _____	<a href="#">Comments</a>
9.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
10.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**Radiation Treatment**

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** TRANSFUSIONS

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/30/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	WITHDRAWAL BY SUBJECT
4.	Specify Status:	[Patient withdrew after motorcycle accident (Undisclosed medical condition)]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Not Started

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Form Status:** Not Started

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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?	

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONTACT OUTCOME - MONTH 1

**Form Status:** Not Started

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1247      **Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
**Subject No:** 12471121      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 18:51

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:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Informed Consent - Asymptomatic Surveillance**

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

**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:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** DISPOSITION - FOLLOW-UP

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	Oct/30/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	WITHDRAWAL BY SUBJECT
4.	Specify Status:	[Patient withdrew after motorcycle accident (Undisclosed medical condition)]

**Header Text:** c4591001

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

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

**Form Status:** Not Started

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

**Form Status:** Not Started

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[Form Comments](#)

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**Treatment Unblinded**

1.	Date Treatment Unblinded :	Not Applicable _____ //	<a href="#">Comments</a>
2.	Primary Reason for Unblinding:	Not Applicable _____	<a href="#">Comments</a>



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** WITHDRAWAL OF CONSENT

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	Oct/30/2020
----	------------------------------	-------------

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** DEATH DETAILS CODED

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[Form Comments](#)

[eCRF Audit Trail History](#)

**Death Details**

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

**Cause of Death**

2.	Cause of Death Status:	Not Applicable _____
	Cause of Death:	Not Applicable _____ [ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Oct/30/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Verified

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Sep-30-2020 17:59:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Sep-30-2020 17:59:47 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
4	Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
5	Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
6	Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
7	Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
8	Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
9	Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Oct-20-2020 09:02:38 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** HEALTH CARE UTILIZATION - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Oct-20-2020 10:48:02 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Respiratory treatment is not applicable Not Applicable
Form	Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Respiratory treatment is not applicable Not Applicable
1	Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Respiratory treatment is not applicable Not Applicable
2	Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Respiratory treatment is not applicable Not Applicable
3	Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
4	Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Respiratory treatment is not applicable Not Applicable
4	Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
5	Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Respiratory treatment is not applicable Not Applicable
5	Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
6	Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Respiratory treatment is not applicable Not Applicable
6	Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Oct-20-2020 10:55:58 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	This is not applicable Not Applicable
Form	Oct-20-2020 09:05:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Oct-20-2020 10:55:58 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	This is not applicable Not Applicable
1	Oct-20-2020 09:05:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Oct-20-2020 10:55:58 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	This is not applicable Not Applicable
2	Oct-20-2020 09:05:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Oct-20-2020 10:55:58 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	This is not applicable Not Applicable
3	Oct-20-2020 09:05:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
4	Oct-20-2020 10:55:58 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	This is not applicable Not Applicable
4	Oct-20-2020 09:05:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Oct-20-2020 10:56:50 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not done - telephonic contact only
Form	Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
4	Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

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**Header Text:** c4591001

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**Subject No:** 12471121

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Form	Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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

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

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**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

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

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Item	Date	User	Comment
Form	Oct-20-2020 10:57:30 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not done - telephonic contact only
Form	Oct-20-2020 09:06:39 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 15-Sep-2020 21:52

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Oct-20-2020 09:06:39 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 15-Sep-2020 21:52

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

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**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2.a	Oct-20-2020 09:06:39 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
2.a	Oct-20-2020 09:06:39 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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

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

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

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**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

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

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Item	Date	User	Comment
Form	Oct-20-2020 10:57:53 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not done - telephonic contact only
Form	Oct-20-2020 09:06:55 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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Item	Date	User	Comment
1	Oct-20-2020 09:06:55 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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Item	Date	User	Comment
2.a	Oct-20-2020 09:06:55 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** OXYGENATION PARAMETERS - Comments

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Oct-20-2020 10:58:10 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not done - telephonic contact only
Form	Oct-20-2020 09:07:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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Oct/05/2020

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**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

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**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Oct-20-2020 09:07:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

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Oct/05/2020

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Item	Date	User	Comment
2	Oct-20-2020 09:07:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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Oct/05/2020

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Item	Date	User	Comment
3	Oct-20-2020 09:07:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

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**Subject No:** 12471121

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

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Item	Date	User	Comment
Form	Oct-20-2020 10:58:33 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not done - telephonic contact only and not indicated
Form	Oct-20-2020 09:07:27 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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Item	Date	User	Comment
4	Oct-20-2020 09:07:27 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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Item	Date	User	Comment
5	Oct-20-2020 09:07:27 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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Item	Date	User	Comment
6	Oct-20-2020 09:07:27 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** IMAGING - Comments

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Item	Date	User	Comment
Form	Oct-20-2020 10:58:56 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not done - telephonic contact only and not indicated
Form	Oct-20-2020 09:07:44 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
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Item	Date	User	Comment
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**Header Text:** c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
4	Oct-20-2020 09:07:44 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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**Visit:** Logs - Unscheduled

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

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**Subject No:** 12471121

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**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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Item	Date	User	Comment
1	Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

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**Site No:** 1247

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Item	Date	User	Comment
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Item	Date	User	Comment
5	Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
6	Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
7	Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
8	Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
9	Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

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**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
10	Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Nov-13-2020 14:28:35 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

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Item	Date	User	Comment
1	Nov-13-2020 14:28:35 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Nov-13-2020 14:28:35 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Nov-13-2020 14:28:35 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
4	Nov-13-2020 14:28:35 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
5	Nov-13-2020 14:28:35 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
4	Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
5	Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
6	Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
7	Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
8	Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
9	Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
10	Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1247

**Subject No:** 12471121

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
4	Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
5	Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1247

**Subject No:** 12471121

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
6	Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** TRANSFUSIONS - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Nov-13-2020 14:29:25 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** TRANSFUSIONS - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Nov-13-2020 14:29:25 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** TRANSFUSIONS - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Nov-13-2020 14:29:25 (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:** 1247

**Subject No:** 12471121

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

**Form:** TREATMENT UNBLINDED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Dec-08-2020 13:37:51 (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:** 1247

**Subject No:** 12471121

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

**Form:** TREATMENT UNBLINDED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Dec-08-2020 13:37:51 (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:** 1247

**Subject No:** 12471121

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

**Form:** TREATMENT UNBLINDED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Dec-08-2020 13:37:51 (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:** 1247

**Subject No:** 12471121

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

**Form:** DEATH DETAILS CODED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Dec-08-2020 13:38:08 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** DEATH DETAILS CODED - Comments

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Dec-08-2020 13:38:08 (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, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-22-2021 11:59:55 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated

**Affidavit:**

N/A

Haylene Nell	Approved	Jan-27-2021 16:38:27 (UTC+02:00) Harare, Pretoria	BOOK	Signed
--------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, HayleneNell, 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-19-2020 08:33:48 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Haylene Nell	Approved	Nov-17-2020 12:35:50 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, HayleneNell, 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 14:28:19 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Haylene Nell	Approved	Nov-12-2020 15:09:38 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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**Affidavit:**

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

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-30-2020 11:19:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 11:19:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**I. Consent Was:**

Date	Location	User	Value	Reason
Sep-30-2020 11:19:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/30/2020	Initial Entry

**Header Text:** c4591001**Visit:** COHORT\_SELECTION**Form Version:** 15-Sep-2020 21:54**Site No:** 1247**Subject No:** 12471121**Generated By:** (b) (4)**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Subject ID**

Date	Location	User	Value	Reason
Sep-30-2020 11:19:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12471121	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-01-2020 21:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-01-2020 07:18:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please clarify as previous query said South Africa may not provide complete DOB
Sep-30-2020 18:36:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please provide complete Birth Date
Sep-30-2020 11:19:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> UNK/UNK/2001	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-30-2020 11:20:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-30-2020 11:20:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR O F SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 11:20:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-30-2020 17:59:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Sep-30-2020 17:59:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-30-2020 17:59:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-30-2020 17:59:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry



**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** HIV STATUS - eCRF Audit Trail History

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Sep-30-2020 18:00:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV P OSITIVE	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Date:**

Date	Location	User	Value	Reason
Sep-30-2020 18:00:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-30-2020 18:00:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 88.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-30-2020 18:00:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-30-2020 18:00:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 183.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-30-2020 18:00:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-30-2020 18:00:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 26.3	Initial Entry

**7.a**

Date	Location	User	Value	Reason
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090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Sep-30-2020 18:00:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.9 <b>Temperature Unit:</b> C <b>Temperature Location::</b> ORAL CAVITY	Initial Entry
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-30-2020 18:00:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Sep-30-2020 18:00:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.9	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Sep-30-2020 18:00:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-30-2020 18:00:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 102046	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:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-01-2020 10:19:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020 18:01:37 (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.
Sep-30-2020 18:01:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Collection:  Sep/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-01-2020 10:19:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BM9CM6	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-01-2020 10:19:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BM9CM6	Initial Entry

Header Text: c4591001  
 Visit: V1\_DAY1\_VAX1\_L  
 Form Version: 22-Apr-2020 21:03  
 Site No: 1247  
 Subject No: 12471121  
 Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
 Audit Trail History  
 Form Status: Data Complete, Locked, Frozen, Verified  
 Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
 Subject Initials: ---  
 Generated Time (GMT): 29-Mar-2021 18:51

5.b

Date	Location	User	Value	Reason
Oct-01-2020 10:20:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSF21	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 10:20:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSF21	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-01-2020 10:20:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSF22	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 10:20:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSF22	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (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:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-30-2020 18:01:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-01-2020 10:20:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020 18:01:58 (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.
Sep-30-2020 18:01:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-01-2020 10:20:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM9CLH	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-01-2020 10:20:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9CLH	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Sep-30-2020 18:02:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-30-2020 18:02:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-30-2020 18:02:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-08-2020 14:06:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-07-2020 14:41:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-05-2020 11:23:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	PDQ RQ1: Thank you for the response. As per section 8.43 of CRF Completion Requirements, please consider updating UNPLANNED VISIT form and select appropriate Contact Outcome option present on UNPLANNED VISIT (UNPL) form.

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Oct-05-2020 09:01:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Pt. to return.
Oct-02-2020 18:41:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Subject has reported with Severe symptoms/reactions on '2020-10-01'. Per protocol, subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form as appropriate. (b) (4)
Sep-30-2020 18:02:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020 11:24	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-30-2020 18:02:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-30-2020 18:02:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-30-2020 18:02:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

Sep-30-2020 18:02:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSER VATION PERIOD	Initial Entry
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**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Sep-30-2020 18:02:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-30-2020 18:02:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471121

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

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

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-21-2020 16:07:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

Header Text: c4591001

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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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Oct/6/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-29-2020 11:31:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Symptom:: FEVER Were fever or systemic sy YES mptoms present on the la Ongoing st day the Subject Diary ? was completed?:  NO  Stop Date:  Oct /6/2 020	Changed Information
Oct-28-2020 15:19:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom:: FEVER Were fever or systemic sy YES mptoms present on the la Ongoing st day the Subject Diary ? was completed?:  NO  Stop Date:  Oct /1/2 020	Transcription error. All other information correct based on diary information
Oct-23-2020 13:19:25	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

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(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	<b>Symptom::</b> FEVER <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES Ongoing ? NO Stop Date: Sep /30/ 2020	
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FEVER <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 13:28:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 11:31:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-29-2020 11:31:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> YES Ongoing? NO Stop Date: Oct/6/2020	Changed Information

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**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 15-Sep-2020 21:56**Site No:** 1247**Subject No:** 12471121**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

Oct-29-2020 11:23:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	eDiary RQ2: Stop Date 1Oct20 for FEVER in Inform is before the last eDiary date 6Oct20. Please review and update as the end date of the event as the last eDiary date if agree. Thanks.
Oct-28-2020 15:19:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription error. All other information correct based on diary information
Oct-28-2020 15:19:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Oct/1/2020	Transcription error. All other information correct based on diary information
Oct-26-2020 14:43:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	eDiary RQ1: Stop Date 30Sep20 for FEVER in Inform is before the last eDiary date 6Oct20. Please review and update as appropriate. Thanks.
Oct-23-2020 13:19:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-23-2020 13:19:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Sep/30/2020	Transcription Error
Oct-22-2020 15:05:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per diary records, FEVER present on Last day however inform entered with 'No' for the same. Please verify

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				and update. If diary entered in error, please enter stop date as last date of diary. Thanks.
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FATIGUE <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES Ongoing ? NO Stop Date: Oct/ 6/2 020	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing? NO Stop Date: Oct/6/2020	Initial Entry

2.c

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEADAC HE <b>Were fever or systemic sy</b> <b>mptoms present on the las</b> <b>t day the Subject Diary wa</b> <b>s completed?:</b> YES Ongoing ? NO Stop Date: Oct/ 6/2 020	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing? NO Stop Date: Oct/6/2020	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH ILL S <b>Were fever or systemic sympto</b> <b>ms present on the last day the S</b> <b>ubject Diary was completed?:</b> NO	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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2.d Symptom:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Oct-21-2020 16:11:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MITI NG Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MITI NG Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (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-21-2020 16:11:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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Header Text: c4591001

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2.f

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIARRH EA <b>Were fever or systemic sy</b> YES <b>mptoms present on the las</b> Ongoing <b>t day the Subject Diary wa</b> ? <b>s completed?:</b> NO  Stop Date:  Oct/ 6/2 020	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Oct/6/2020	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENE D MUSCL E PAIN	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENERED JOINT PAIN  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

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Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RED NES S <b>Were injection site reactions pr</b> NO <b>esent on the last day the Subjec</b> <b>t Diary was completed?:</b>	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLIN G	Initial Entry

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			Were injection site reactions present on the last day the Subject Diary was completed?:	NO
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**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 16:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Header Text: c4591001

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Subject No: 12471121

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

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**1. Date:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 37.2 <b>Temperature Unit:</b> C <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.2	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

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**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 15-Sep-2020 21:51**Site No:** 1247**Subject No:** 12471121**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

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Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-21-2020 16:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (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:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-21-2020 16:11:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-22-2020 09:56:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 16:11:54 (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-21-2020 16:11:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Collection:  Oct/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-22-2020 09:56:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BM9D1T	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-22-2020 09:56:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BM9D1T	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Oct-21-2020 16:12:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-21-2020 16:12:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-21-2020 16:12:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-30-2020 07:48:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	UNPL updated
Oct-29-2020 11:06:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Query 1: Answered	Unplanned visit was performed on 28 Oct 2020. New UNPL visit page will be completed today.
Oct-29-2020 08:34:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Subject has reported with Severe symptoms/reactions on '2020-10-27'. Per protocol, subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

				as appropriate. (b) (4)
Oct-21-2020 16:12:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/21/2020 1 0:17	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-21-2020 16:12:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-21-2020 16:12:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-21-2020 16:12:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-21-2020 16:12:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSER VATION 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-21-2020 16:12:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Oct-13-2020 08:20:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-13-2020 08:16:06 (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.
Oct-13-2020 08:16:06 (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.
Oct-13-2020 08:16:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/5/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 08:16:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Not Complete**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/5/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/1/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-22-2021 19:34:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-22-2021 11:59:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-22-2021 11:59:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Oct/7/2020	New Information
Feb-15-2021 13:15:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please confirm the symptoms are still ongoing for this COVID Illness. If all symptoms for this illness are resolved; please update the Last Symptoms Resolved Date else clarify.
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> YES	Initial Entry
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4.a Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASE D COUGH <b>Symptom Pr</b> NO <b>esent:</b>	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED S	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			s: HORTNESS OF BREATH Symptom NO Present:	
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4.c Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Symptom P YES resent:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED MUSCLE PAI N	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL  <b>Symptom Pr</b> NO <b>esent:</b>	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-13-2020 08:19:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Symptoms:</b> NEW OR INCREASED SORE THROAT	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Not Complete**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

			<b>Symptom P NO resent:</b>	
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SORE THROAT <b>Symptom P resent:</b>	Initial Entry

**4.g Symptoms:**

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Oct-13-2020 08:19:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> YES	Initial Entry

**4.h Symptoms:**

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.i**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry
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**4.i Symptoms:**

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Oct-13-2020 08:18:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Oct-20-2020 09:02:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020**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:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-13-2020 08:20:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-13-2020 08:20:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-13-2020 08:22:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 08:20:00 (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-13-2020 08:20:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Collection:  Oct/5/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-13-2020 08:22:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> CV24081	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-13-2020 08:22:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> CV24081	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**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:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-20-2020 09:02:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Oct-20-2020 09:03:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Only self swab done.	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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*I.a*

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALI ST <b>Occurrence of Visits or C</b> NO <b>ontacts:</b>	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits</b> NO <b>or Contacts:</b>	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***I.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.c***

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.d***

Date	Location	User	Value	Reason
Oct-20-2020 09:04:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Oct-20-2020 09:04:11	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	<b>Type of Practitioner:</b> URGENT CARE	
			<b>Occurrence of Visits or Contacts:</b>	

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-20-2020 09:04:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

*I.f*

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHE R <b>Occurrence of Visits or Cont</b> NO <b>acts:</b>	Initial Entry

*I.f Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

*I.f Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2. Other Type of Practitioner Specify:*

Date	Location	User	Value	Reason
Oct-20-2020 10:48:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 09:04:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Ongoing?**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-20-2020 10:55:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-20-2020 09:04:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-20-2020 10:55:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-20-2020 09:05:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Oct-20-2020 10:55:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-20-2020 09:05:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Oct-20-2020 10:55:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-20-2020 09:05:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-20-2020 10:55:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-20-2020 09:05:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020  
**Form Version:** 15-Sep-2020 21:51  
**Site No:** 1247  
**Subject No:** 12471121  
**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry

**5.a Sponsor ID:**

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Lab Normal Range:</b>	Not Done
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**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Generated Time (GMT): 29-Mar-2021 18:51

Pretoria	(b) (4), (b) (6)	:	e	
		Test::	Not Done	
		Result::	Not Done	
		Not Done::	Not Done	
		Lab Normal Range:	Not Done	

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.e

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done <b>:</b> e <b>Test::</b> Not Done e <b>Result::</b> Not Done e <b>Not Done::</b> Not Done e <b>Lab Normal Range:</b> Not Done e	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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Form Version: 15-Sep-2020 21:51

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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Form Version: 15-Sep-2020 21:51

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Site No: 1247

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Subject No: 12471121

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Lab Normal Range:</b>	Not Done
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5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

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Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-20-2020 09:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry

**5.a Sponsor ID:**

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done	Initial Entry

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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Site No: 1247

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Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Lab Normal Range:</b>	Not Done
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

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			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done	Initial Entry

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Site No: 1247

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Generated Time (GMT): 29-Mar-2021 18:51

Pretoria	(b) (4), (b) (6)	:	e	
		Test::	Not Done	
		Result::	Not Done	
		Not Done::	Not Done	
		Lab Normal Range:	Not Done	

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (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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Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done <b>:</b> e <b>Test::</b> Not Done e <b>Result::</b> Not Done e <b>Not Done::</b> Not Done e <b>Lab Normal Range:</b> Not Done e	Initial Entry



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Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Lab Normal Range:</b>	Not Done
--	--	--	--------------------------	----------

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Pretoria	(b) (4), (b) (6)	:	e	
		Test::	Not Done	
		Result::	Not Done	
		Not Done::	Not Done	
		Lab Normal Range:	Not Done	

5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (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
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done <b>:</b> e <b>Test::</b> Not Done e <b>Result::</b> Not Done e <b>Not Done::</b> Not Done e <b>Lab Normal Range:</b> Not Done e	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done <b>Result::</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

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: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j Not Done:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
**Form Version:** 15-Sep-2020 21:52 **Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1247 **Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
**Subject No:** 12471121 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Systolic::</b> Not Done <b>Diastolic::</b> Not Done <b>Respiratory Rate in respirations/minute:</b> Not Done <b>Heart Rate in beats/minute:</b> Not Done	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Respiratory Rate in respirations/minute:**



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

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

**Form Version:** 15-Sep-2020 21:52

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-20-2020 09:06:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

*2.a Heart Rate in beats/minute:*

Date	Location	User	Value	Reason
Oct-20-2020 09:06:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**I. Date:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> Not Done <b>Oxygen Saturation:</b> Not Done	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Oct-20-2020 09:06:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

**Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Oct-20-2020 09:07:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Oct-20-2020 09:07:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Oct-20-2020 09:07:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/05/2020**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-20-2020 09:07:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-20-2020 09:07:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 09:07:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Oct-20-2020 09:07:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Oct-20-2020 09:07:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Oct-20-2020 09:07:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/05/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-20-2020 09:07:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Oct-20-2020 09:07:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Oct-20-2020 09:07:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Oct-20-2020 09:07:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/01/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-07-2020 14:36:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/1/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/01/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**I. Assessments**

Date	Location	User	Value	Reason
Oct-07-2020 14:41:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 14:37:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-07-2020 14:37:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/01/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Contact Type:**

Date	Location	User	Value	Reason
Oct-07-2020 14:41:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Oct-07-2020 14:41:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Oct/1/2020  Contact Outcome:  VISIT NOT REQUIRED, INVESTI GATOR DECISION	Initial Entry

**3. Comments:**

Date	Location	User	Value	Reason
Oct-07-2020 14:41:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Patient contacted 01, 02 and 05 Oct. Pati ent advised to do home swab 05 Oct - pa tient symptoms were improving and pati ent was not limited in her activities	Initial Entry



**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on  
Oct/02/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-23-2020 12:09:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/2/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on  
Oct/02/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**I. Assessments**

Date	Location	User	Value	Reason
Oct-23-2020 12:10:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-23-2020 12:09:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-23-2020 12:09:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 2 - Unscheduled Visit on  
Oct/02/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Contact Type:**

Date	Location	User	Value	Reason
Oct-23-2020 12:10:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Oct-23-2020 12:10:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Oct/2/2020  Contact Outcome:  VISIT NOT REQUIRED, INVESTI GATOR DECISION	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Oct/05/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-23-2020 12:11:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/5/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Oct/05/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**I. Assessments**

Date	Location	User	Value	Reason
Oct-23-2020 12:14:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-23-2020 12:11:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-23-2020 12:11:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 3 - Unscheduled Visit on  
Oct/05/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Contact Type:**

Date	Location	User	Value	Reason
Oct-23-2020 12:14:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Oct-23-2020 12:14:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Oct/5/2020  Contact Outcome:  VISIT ARRANGED, BUT NOT AT TENDED	Initial Entry

**3. Comments:**

Date	Location	User	Value	Reason
Oct-23-2020 12:14:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pt. invited for consultation, pt. doesn't f eel its necessary.	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 4 - Unscheduled Visit on  
Oct/21/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-29-2020 13:37:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 4 - Unscheduled Visit on  
Oct/21/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**I. Assessments**

Date	Location	User	Value	Reason
Oct-29-2020 13:38:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-29-2020 13:37:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-29-2020 13:37:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)



Header Text: c4591001

Visit: Unplanned 4 - Unscheduled Visit on Oct/21/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**I. Contact Type:**

Date	Location	User	Value	Reason
Oct-29-2020 13:38:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Oct-29-2020 13:39:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-29-2020 13:39:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Oct/21/2020  Contact Outcome:  VISIT NOT REQUIRED, INVESTI GATOR DECISION	Transcription Error
Oct-29-2020 13:38:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Contact 05/Oct/2020 is not equal to the Date of Visit 21/Oct/2020 within same unplanned visit. Please review and update as appropriate.
Oct-29-2020 13:38:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Oct/5/2020  Contact Outcome:  VISIT NOT REQUIRED, INVESTI GATOR DECISION	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 5 - Unscheduled Visit on  
Oct/23/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-26-2020 16:17:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/23/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 5 - Unscheduled Visit on  
Oct/23/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**I. Assessments**

Date	Location	User	Value	Reason
Oct-26-2020 16:20:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-26-2020 16:19:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-26-2020 16:19:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 5 - Unscheduled Visit on  
Oct/23/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Contact Type:**

Date	Location	User	Value	Reason
Oct-26-2020 16:20:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Oct-26-2020 16:20:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact: Oct/23/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTI GATOR DECISION	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on  
Oct/24/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**I. Date of Visit**

Date	Location	User	Value	Reason
Oct-26-2020 16:20:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/24/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on  
Oct/24/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**I. Assessments**

Date	Location	User	Value	Reason
Oct-26-2020 16:22:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-26-2020 16:21:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-26-2020 16:21:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 6 - Unscheduled Visit on  
Oct/24/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**I. Contact Type:**

Date	Location	User	Value	Reason
Oct-26-2020 16:21:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Oct-26-2020 16:22:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-26-2020 16:22:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact: Oct/24/2020 Contact Outcome: VISIT NOT ARRANGED, REACTI ON NO LONGER PRESENT	Transcription Error
Oct-26-2020 16:21:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Contact" is missing.
Oct-26-2020 16:21:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Contact Outcome: VISIT NOT ARRANGED, REACTI ON NO LONGER PRESENT	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on  
Oct/28/2020

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

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-29-2020 11:06:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Oct/28/2020	Initial Entry



**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on  
Oct/28/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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*I. Assessments*

Date	Location	User	Value	Reason
Oct-29-2020 11:07:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-29-2020 11:06:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-29-2020 11:06:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 7 - Unscheduled Visit on  
Oct/28/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51

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**I. Contact Type:**

Date	Location	User	Value	Reason
Oct-29-2020 11:07:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Oct-29-2020 11:07:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-29-2020 11:07:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> YES Date of Contact:  Oct/28/2020  Contact Outcome:  VISIT NOT REQUIRED, INVEST IGATOR DECISION	Transcription Error
Oct-29-2020 11:07:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Contact" is missing.
Oct-29-2020 11:07:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> YES Contact Outcome:  VISIT NOT REQUIRED, INVEST IGATOR DECISION	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

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

**Form Status:**

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Nov-03-2020 13:23:26 (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:** 1247

**Subject No:** 12471121

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

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

**Form Status:**

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Nov-05-2020 12:33:58 (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: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Flail Chest	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Dec-03-2020 09:42:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: C losed	Response satisfies query
Dec-02-2020 10:39:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 4: C losed	Auto closed by Validation Check: VC_AE001_10_AN
Dec-02-2020 07:19:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: A nswered	Ongoing at EOT - has recovered since
Dec-02-2020 07:17:06	ACV0PFEINFP6000	auto query (autoquery)	Query 5: O pened	'Disposition Follow-up form is completed and this

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

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(UTC+02:00) Harare, Pretoria				Adverse Event is still ongoing. Please review and update as appropriate.
Dec-02-2020 07:17:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 4: A nswered	Transcription Error
Dec-02-2020 07:17:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entr</b> <b>y:</b> YES	Transcription Error
Dec-01-2020 18:30:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 4: O pened	DMW6283890; 'End Date' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Dec-01-2020 11:36:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entr</b> <b>y:</b> NO End Date Time:  Nov/13/ 2020 U NK:UN K	New Information
Nov-24-2020 07:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: C losed	Response satisfies query
Nov-23-2020 21:05:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: C losed	Auto closed by Validation Check: VC_AE001_10_AN
Nov-23-2020 12:45:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: A nswered	Updated as per query request
Nov-23-2020 12:44:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: O pened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Nov-23-2020 12:44:25	ACV0PFEINFP6000	auto query (autoquery)	Query 2: A nswered	Updated as per query

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(UTC+02:00) Harare, Pretoria				
Nov-23-2020 12:44:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Updated as per query
Nov-23-2020 09:24:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	If the adverse event has is not confirmed as resolved at the time of data collection select YES. Or clarify.
Nov-20-2020 11:20:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Patient was contacted to confirm end date of SAE
Nov-19-2020 16:28:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW5422404; 'End Date' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Nov-13-2020 14:30:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Nov/13/2020 UNK:UNK	New Information
Nov-06-2020 16:38:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-05-2020 12:31:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ongoing
Nov-04-2020 19:15:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify if AE is still ongoing or if it has resolved. If resolved- please enter stop date.
Nov-03-2020 13:23:26 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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Harare, Pretoria

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-04-2020 12:32:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Flail Chest: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Is this serious event associated with co ngenital anomaly or birth defect?  NO  Did this serious event result in death?  NO  Did this serious event require or prolon g hospitalization?  YES  Did this serious event result in persiste nt or significant disability/incapacity?  NO  Is this serious event life threatening?	Initial Entry

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			NO	
			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
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-05-2020 18:43:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-05-2020 12:34:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	As requested
Nov-04-2020 18:07:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Per the CRF Completion Guidelines (ver 9) when a motor vehicle accident (MVA) results in an injury, both the injury and the MVA should be recorded as AEs thus please enter 'motorcycle accident' as a separate AE. Thank you.
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  Flail chest secondary to motorcycle accident	Initial Entry

10. Latest Action Taken with Study Treatment:

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Date	Location	User	Value	Reason
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**II. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 14:37:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Acceptable discrepancy
Dec-22-2020 15:17:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Candidate	For Clinical review
Dec-21-2020 07:03:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Per previous queries and communications, outcome should be not recovered as outcome was still not recovered at the time that patient withdrew from the study
Dec-18-2020 15:29:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Opened	Per CRFCG Section 8.50.12.Record the appropriate outcome of the event in relation to the Participant's status.".Since in the last interaction between PI and subject was reported "she was fully recovered",the outcome should be Recovered/resolved in both DB

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Dec-09-2020 12:50:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Candidate	PSSR review
Dec-08-2020 11:38:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	EDC confirmed correct. Follow up report was sent on 27 Nov 2020, as per previous query response
Dec-04-2020 07:59:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Opened	SAE RECON 1: Per narrative of the case ffp on 17Nov2020 indicates'(SAE outcome updated to recovered on 13Nov2020).If the correct outcome is not recovered/not resolved,please submit a follow up form to provide correct outcome.
Dec-03-2020 06:34:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Updated report was sent 27 Nov 2020 - with out come as not recovered
Dec-02-2020 14:12:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	SAE RECON:AER#2020428199 outcome was reported as NOT RECOVERED/NOT RESOLVED on AE CRF while reported as RECOVERED/RESOLVED Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Dec-02-2020 07:17:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLV ED	Transcription Error
Dec-01-2020 13:29:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Dec-01-2020 13:29:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Deleted	Transcription Error

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

Date	Location	User	Value	Reason
Dec-01-2020 13:29:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : RECOVERED/RESOLVED	Transcription Error
Dec-01-2020 13:28:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued: Candidate	Pending SDB update
Dec-01-2020 11:36:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	For AE Flail Chest: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-27-2020 12:43:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Updated report sent
Nov-27-2020 11:47:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued: Opened	SAE RECON 1: Outcome still reported as RECOVERED/RESOLVED in Safety database.If correct outcome is RECOVERING/RESOLVING, please submit a follow up AEM form to update outcome in Safety database.
Nov-25-2020 14:49:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued: Candidate	pending SDB update
Nov-25-2020 14:36:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Updated SAE report sent

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Nov-25-2020 12:06:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Op ened	SAE RECON:AER#2020428199 outcome was updated to RECOVERING/RESOLVING on AE CRF while reported as RECOVERED/RESOLVED Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-24-2020 16:34:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Clo sed	Auto closed by Validation Check: VC_AE001_35
Nov-24-2020 12:16:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Ans wered	Transcription Error
Nov-24-2020 12:16:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : RECO VERI NG/R ESOL VING	Transcription Error
Nov-23-2020 21:06:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Op ened	DMW5549978;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Nov-17-2020 16:58:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Per PSSR confirmation during the meeting, follow up form received. Outcome will be updated to recovered/resolved
Nov-17-2020 15:11:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Rei ssued: Candi date	For PSSR confirmation
Nov-17-2020 15:02:58	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans	SAE follow up report was sent and only cover page was received.

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(UTC+02:00) Harare, Pretoria			wered	Report to be resent
Nov-17-2020 12:48:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	SAE RECON:Per PSSR confirmation 'No new update received, outcome still recovering/resolving'. If correct outcome is 'RECOVERED/RESOLVED',please submit a follow up AEM form to indicate updated outcome in Safety database.
Nov-16-2020 14:59:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Candidate	Pending SDB update/For PSSR confirmation.
Nov-16-2020 12:30:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Follow up form completed and to be sent
Nov-14-2020 15:58:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020428199 outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/Resolving in Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Nov-13-2020 18:06:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-13-2020 18:06:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : RECOVERED/RESOLVED	Changed Information
Nov-13-2020 14:30:14 (UTC+02:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Flail Chest: Response to "What was the outcome of this adverse event?" is

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Harare, Pretoria				'Recovering/Resolving' but AE End Date/Time is present.
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> RECOVERING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 09:26:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	New Information
Nov-30-2020 19:30:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Nov-30-2020 19:30:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Nov-26-2020 16:43:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Patient did not withdraw from study due to unrelated medical condition. Patient withdrew from study after she was in a motorcycle accident
Nov-26-2020 09:33:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Patient does not wish to disclose any other medical conditions
Nov-25-2020 22:30:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	GPD CLIN: Per the SAE form on 03NOV2020, the subject requested withdrawal from the study due to an unrelated medical condition. If AE of 'flail chest' did not result in study discontinuation update both the AE and DISPOSITION FOLLOW UP CRFs as

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Nov-25-2020 22:29:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	GPD CLIN: Per the SAE form on 03NOV2020, the subject requested withdrawal from the study due to an unrelated medical condition. Please specify what condition resulted in study discontinuation. Thank you.
Nov-25-2020 22:28:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	fixed error and will reissue
Nov-25-2020 22:25:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	GPD CLIN: Per the SAE form the subject on 03NOV2020, the subject requested withdrawal from the study due to an unrelated medical condition. Please specify what condition resulted in study discontinuation. Thank you.
Nov-20-2020 07:25:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-19-2020 08:34:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	FUP form updated
Nov-19-2020 04:10:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 3: Opened	Per previous query, subject withdrew from study, please enter the FUP form indicating ADVERSE EVENT if this AE was the reason for discontinuation.
Nov-14-2020 17:42:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-14-2020 09:27:32 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	EOT form entered

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Pretoria				
Nov-14-2020 05:16:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 2: Opened	If the subject withdrew, please enter EOT/FUP forms. Otherwise, please update this question to NO.
Nov-12-2020 17:57:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 08:09:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient withdrew from study after AE occurred
Nov-11-2020 06:42:07 (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? YES, However, subject completed all vaccinations and continued after the Adverse Event. Please consider changing the response to NO. Or else clarify.
Nov-03-2020 13:23:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-04-2020 12:32:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020428199	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-16-2020 17:42:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Nov-16-2020 11:28:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient was not hospitalized due to motorcycle accident. Patient experienced flail chest after accident and was then hospitalized based on flail chest
Nov-14-2020 22:41:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	If the subject was hospitalized due to event, this meets seriousness criteria. Thank you.
Nov-14-2020 13:02:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	To be confirmed and updated
Nov-13-2020 21:11:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per case narrative, MVA was associated with hospitalization. Please revise/update this form accordingly. Thank you
Nov-05-2020 12:33:58 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Motorcyle accident	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Pretoria

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date Time:  Oct/30/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-15-2020 15:20:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-15-2020 12:49:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Changed Information
Dec-15-2020 12:06:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-15-2020 12:06:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Transcription Error
Dec-09-2020 16:01:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: per protocol grade 4 toxicity meets definition for SAE reporting, pls either submit SAE form to sponsor immediately or advise if initial grading was an error and update CRF accordingly. Thanks
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 4	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  Motorcycle accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-05-2020 12:35:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-05-2020 12:35:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Nov-05-2020 12:33:58 (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'.
Nov-05-2020 12:33:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Medication Error (Type of Medication Error):**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Start Date:**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Is the medication error still ongoing?**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**7. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
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090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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8. Did the Medication Error cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

9. Was this medication error associated with any adverse events?

Date	Location	User	Value	Reason
Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

10. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-13-2020 14:28:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Date	Location	User	Value	Reason
Nov-13-2020 14:28:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-13-2020 14:28:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Nov-13-2020 14:28:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)



**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1247**Subject No:** 12471121**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Dose:**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Dose Unit:**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**7. Dose Frequency:**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Route:**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Start Date:**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**10. Ongoing?**

Date	Location	User	Value	Reason
Nov-13-2020 14:28:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471121

Generated By: (b) (4)

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Nov-13-2020 14:29:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471121

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Transfusion Type:**

Date	Location	User	Value	Reason
Nov-13-2020 14:29:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Date of Transfusion:**

Date	Location	User	Value	Reason
Nov-13-2020 14:29:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001**Visit:** End of Treatment - Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471121**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-14-2020 22:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-14-2020 21:37:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-14-2020 21:37:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020	Transcription Error
Nov-14-2020 17:43:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please confirm why date is 21OCT2020 as MVA occurred on 30OCT2020
Nov-14-2020 09:26:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-14-2020 09:26:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-14-2020 09:27:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-14-2020 09:26:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is WITHDRAWAL BY SUBJECT but "Specify Status" is missing.
Nov-14-2020 09:26:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WITHDRAWAL BY SUBJECT	Initial Entry

**4. Specify Status:**

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1247

**Subject No:** 12471121

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Dec-01-2020 12:50:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Patient withdrew after motorcycle accident (Undisclosed medical condition)	Changed Information
Nov-14-2020 09:27:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Patient withdrew from study after motorcycle accident	Initial Entry

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-19-2020 08:33:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-19-2020 08:33:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-01-2020 12:50:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-01-2020 12:48:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is WITHDRAWAL BY SUBJECT but "Specify Status" is missing.
Dec-01-2020 12:48:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WITHDRAWAL BY SUBJECT	Changed Information
Nov-19-2020 08:33:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Dec-01-2020 12:50:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Patient withdrew after motorcycle accid ent (Undisclosed medical condition)	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1247

**Subject No:** 12471121

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Dec-08-2020 13:37:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Dec-08-2020 13:37:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1247

**Subject No:** 12471121

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**I. Withdrawal of Consent Date :**

Date	Location	User	Value	Reason
Dec-08-2020 21:44:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-08-2020 11:36:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Dec-08-2020 11:36:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020	Initial Entry
Dec-04-2020 23:22:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLIN: Per the DISPOSITION TREATMENT CRF the subject discontinued treatment due to 'withdrawal by subject' thus please complete the WITHDRAWAL OF CONSENT CRF. Thank you.

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1247

**Subject No:** 12471121

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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***1. Date of Collection / Notification of Death:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-08-2020 13:38:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b><u>Data Entry:</u></b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471121

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Subject Status**

Date	Location	User	Value	Reason
Dec-01-2020 12:48:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Changed Information
Nov-19-2020 08:33:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Nov-14-2020 09:26:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Sep-30-2020 18:01:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-30-2020 17:59:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Dec-01-2020 12:48:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/30/2020	Changed Information
Nov-19-2020 08:33:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/30/2020	Initial Entry
Nov-14-2020 21:37:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/30/2020	Transcription Error
Nov-14-2020 09:26:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/21/2020	Initial Entry
Sep-30-2020 18:01:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/30/2020	Initial Entry
Sep-30-2020 17:59:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

090177e196ae2fc0\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Verified

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471121

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-11-2020 12:26:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry