

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

**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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1247

**Subject No:** 12471220

**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 Oct/8/2020
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**Header Text:** c4591001  
**Visit:** COHORT\_SELECTION **Form:** DEMOGRAPHY  
**Form Version:** 15-Sep-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1247 **Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
**Subject No:** 12471220 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12471220]
2.	Birth Date:	UNK/UNK/1976
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:** 12471220

**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/8/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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 _____
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**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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	Oct/8/2020
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:** 12471220

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

**Form:** GENERAL MEDICAL 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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Temporal lobe Epilepsy]
	Start Date:	UNK/UNK/2001
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bilateral tubal ligation Sterilized]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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
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**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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:	Oct/8/2020
2.	Weight:	[109.0]
3.	Unit:	kg
4.	Height:	[164.0]
5.	Unit:	cm
6.	Body Mass Index:	[40.5]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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/8/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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 :	Oct/8/2020
2.	Randomization Number:	[104594]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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: Oct/8/2020
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	[BM9CV8]
5.b	Sample ID	[BRSTG2]
5.c	Sample ID	[BRSTG5]

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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/8/2020
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	[BM9CV2]
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090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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/8/2020 09:38
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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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	NO - REACTOGENICITY E-DIARY NOT 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:** 12471220

**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/28/2020
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471220

**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/28/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471220

**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/28/2020
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:	

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471220

**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/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BM9FKT]
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090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471220

**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/28/2020 11:09
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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** DATE OF VISIT

**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](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/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	[BR7MSB]
5.b	Sample ID	[BRY9S5]
5.c	Sample ID	[BRY9S6]

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1247

**Subject No:** 12471220

**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:** 12471220

**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:** 12471220

**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:** 12471220

**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:** 12471220

**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:** 12471220

**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:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Dec/24/2020

**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:** 12471220

**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	Dec/24/2020
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 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**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:	Dec/24/2020
2.	Date of First Symptom Started:	Dec/22/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/26/2020

**Symptoms**

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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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**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:** 12471220

**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    **Form:** MICROBIOLOGY SPECIMEN  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**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>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Dec/24/2020

**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:** 12471220

**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: Dec/24/2020
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	[CV48884]
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090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB on Dec/24/2020

**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:** 12471220

**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
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Self-swab collected]

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** HEALTH CARE UTILIZATION  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**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:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**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:** 12471220

**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>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**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>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**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?	YES Respiratory Illness Diagnosis: [Pharyngitis]  Date of Diagnosis: Dec/24/2020
3.	Toxicity Grade:	1

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**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:** 12471220

**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    **Form:** ILLNESS DETAILS - SEVERE  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**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: 12471220

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	Sponsor-Defined Identifier	Test:	Result:	<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	

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Dec/24/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

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

**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>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (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: 12471220

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	

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

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

**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>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit    Form: LOCAL LABORATORY DATA - REPEATING Hematology  
on Dec/24/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**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>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (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:** 12471220

**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    **Form:** VITAL SIGNS - COVID  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

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

**Vital Signs**

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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (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:** 12471220

**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    **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Not Done _____ //	<a href="#">Comments</a>
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**Vital Signs Details**

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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (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:** 12471220

**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    **Form:** OXYGENATION PARAMETERS  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**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>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (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:** 12471220

**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>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

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

**Concomitant Medications**

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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (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:** 12471220

**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    **Form:** IMAGING  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**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>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Jan/21/2021

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

**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:** 12471220

**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	Jan/21/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Jan/21/2021

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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:** 12471220

**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	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/21/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR7MTD]
5.b	Sample ID	[BRY9VT]
5.c	Sample ID	[BRY9VV]

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**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:** 12471220

**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:	
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**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1247

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

**Subject No:** 12471220

**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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090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/30/2020

**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:** 12471220

**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/30/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/30/2020

**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:** 12471220

**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/30/2020

**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:** 12471220

**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/30/2020  Contact Outcome: VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY
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: 12471220

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	Diarrhea	Oct/9/2020 UNK: UNK	NO End Date Time:  Oct/10/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Headaches	Oct/29/2020 UNK :UNK	NO End Date Time:  Oct/29/2020 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Generalized Joint pain	Oct/29/2020 UNK :UNK	NO End Date Time:  Oct/29/2020 UNK:UNK	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Left axillary lymphadenopathy	Oct/29/2020 UNK :UNK	NO End Date Time:  Nov/2/2020 UNK:UNK	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	Generalized Joint pain	Oct/30/2020 UNK :UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**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)	[Headaches]
4.	Start Date Time:	Oct/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/29/2020 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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**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:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Generalized Joint pain]
4.	Start Date Time:	Oct/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/29/2020 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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**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:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left axillary lymphadenopathy]
4.	Start Date Time:	Oct/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/2/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data 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:	[5]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Generalized Joint pain]	<a href="#">Comments</a>
4.	Start Date Time:	Oct/30/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	2	
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	RELATED	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	YES	
12.	Was a Non-Drug Treatment given?	NO	

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**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:** 12471220

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** MEDICATION ERROR

**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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**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>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**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:** 12471220

**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:** 12471220

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

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

**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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**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>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (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:** 12471220

**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:** 12471220

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**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>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**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:** 12471220

**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:** 12471220

**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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**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>

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**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:** 12471220

**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:** 12471220

**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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** DISPOSITION - 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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Nov/30/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1247

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

**Subject No:** 12471220

**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:** 12471220

**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:** 12471220

**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:	

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**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:** 12471220

**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?	

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1247

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

**Subject No:** 12471220

**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:** 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:** 12471220

**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:** 12471220

**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:** 12471220

**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:** 12471220

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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**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:** 12471220

**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:** Follow-Up - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1247

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

**Subject No:** 12471220

**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	Jan/27/2021
2.	Erroneous Visit	



**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

**Form Status:** Data Complete, Frozen

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

**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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/27/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Data Complete, 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](#)

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** DEATH DETAILS CODED

**Form Status:** Data Complete, 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 Version:** 22-Apr-2020 21:03

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/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:** 12471220

**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>
----	--------------------	--------------------------------------

**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:** 12471220

**Subject Initials:** ---

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

**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
------	-------------------	------	------	--------

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-08-2020 12:51:40 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2	Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
3	Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
4	Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5	Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
6	Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Dec/24/2020

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

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**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
7	Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

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on Dec/24/2020

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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 18:51

[Back to Form](#)

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

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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on Dec/24/2020

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

**Form Status:** Data Complete

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**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
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**Header Text:** c4591001

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on Dec/24/2020

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

[Back to Form](#)

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

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[Back to Form](#)

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[Back to Form](#)

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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

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

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**Subject No:** 12471220

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

[Back to Form](#)

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

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
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**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5.e	Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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

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

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

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 18:51

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

Item	Date	User	Comment
1	Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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

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**Subject No:** 12471220

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
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**Form Version:** 15-Sep-2020 21:55

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**Subject No:** 12471220

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
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**Subject No:** 12471220

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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

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

[Back to Form](#)

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

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

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

[Back to Form](#)

Item	Date	User	Comment
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**Form Version:** 15-Sep-2020 21:55

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

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

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

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5 f	Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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

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

**Form Status:** Data Complete

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**Subject No:** 12471220

**Subject Initials:** ---

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

[Back to Form](#)

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

[Back to Form](#)

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

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

Item	Date	User	Comment
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on Dec/24/2020

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

[Back to Form](#)

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on Dec/24/2020

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

[Back to Form](#)

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

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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**Subject No:** 12471220

**Subject Initials:** ---

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

[Back to Form](#)

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**Subject No:** 12471220

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

[Back to Form](#)

Item	Date	User	Comment
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on Dec/24/2020

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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
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on Dec/24/2020

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

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

[Back to Form](#)

Item	Date	User	Comment
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on Dec/24/2020

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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
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on Dec/24/2020

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

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
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**Form Version:** 06-Jul-2020 21:55

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

[Back to Form](#)

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

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[Back to Form](#)

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

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

[Back to Form](#)

Item	Date	User	Comment
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**Subject No:** 12471220

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
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on Dec/24/2020

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-24-2020 14:04:20 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING - Comments  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Dec-24-2020 14:04:20 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2	Dec-24-2020 14:04:20 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments  
on Dec/24/2020

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

**Form Status:** Data Complete

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

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**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
3	Dec-24-2020 14:04:20 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING - Comments  
on Dec/24/2020

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

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
4	Dec-24-2020 14:04:20 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT - Comments

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Dec-01-2020 10:19:36 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not considered COVID related as it was 1 day post vaccine

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** MEDICATION ERROR - 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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-01-2020 13:17:24 (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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**Subject No:** 12471220

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

**Form:** MEDICATION ERROR - 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

[Back to Form](#)

Item	Date	User	Comment
1	Dec-01-2020 13:17:24 (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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**Subject No:** 12471220

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

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[Back to Form](#)

Item	Date	User	Comment
2	Dec-01-2020 13:17:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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[Back to Form](#)

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**Visit:** Logs - Unscheduled

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[Back to Form](#)

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

Item	Date	User	Comment
5	Dec-01-2020 13:17:24 (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

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

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[Back to Form](#)

Item	Date	User	Comment
6	Dec-01-2020 13:17:24 (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:** 12471220

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

[Back to Form](#)

Item	Date	User	Comment
7	Dec-01-2020 13:17:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
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**Header Text:** c4591001

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[Back to Form](#)

Item	Date	User	Comment
10	Dec-01-2020 13:17:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-01-2020 13:17:55 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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**Site No:** 1247

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

Item	Date	User	Comment
5	Dec-01-2020 13:17:55 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-01-2020 13:18:26 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

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

[Back to Form](#)

Item	Date	User	Comment
1	Dec-01-2020 13:18:26 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

Item	Date	User	Comment
6	Dec-01-2020 13:18:26 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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**Form:** 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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-01-2020 13:18:44 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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[Back to Form](#)

Item	Date	User	Comment
1	Dec-01-2020 13:18:44 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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[Back to Form](#)

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

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

**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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-01-2020 13:19:01 (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:** 12471220

**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

[Back to Form](#)

Item	Date	User	Comment
1	Dec-01-2020 13:19:01 (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:** 12471220

**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

[Back to Form](#)

Item	Date	User	Comment
2	Dec-01-2020 13:19:01 (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:** 12471220

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

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-23-2021 13:33:42 (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:** 12471220

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

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-23-2021 13:33:42 (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:** 12471220

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

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-23-2021 13:34:09 (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:** 12471220

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

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-23-2021 13:34:09 (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:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

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-23-2021 13:32:14 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated

**Affidavit:**

N/A

Haylene Nell	Approved	Jan-27-2021 15:01:24 (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-30-2020 10:40:54 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Haylene Nell	Approved	Nov-12-2020 21:07:54 (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.

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1247

**Subject No:** 12471220

**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

[Back to Form](#)

**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Oct-08-2020 11:35:51 (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
Oct-08-2020 11:35:51 (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:** 12471220

**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

[Back to Form](#)

**I. Consent Was:**

Date	Location	User	Value	Reason
Oct-08-2020 11:37:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Oct/8/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1247

Subject No: 12471220

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
Oct-08-2020 11:35:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12471220	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-08-2020 11:35:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> UNK/UNK/1976	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-08-2020 11:37:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Oct-08-2020 11:37:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 11:37:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-08-2020 12:51:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/8/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Oct-08-2020 12:51:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/8/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-08-2020 12:51:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-08-2020 12:51:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Oct-12-2020 10:42:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Line/MH Number: 1 <b>Medical History Term:</b> Temporal lobe Epilepsy <b>Start Date:</b> UNK/UNK/2001 <b>Ongoing:</b> YES	Transcription Error
Oct-08-2020 12:52:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 1 <b>Medical History Term:</b> Epilepsy <b>Start Date:</b> UNK/UNK/2001 <b>Ongoing:</b> YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-08-2020 12:52:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-12-2020 12:38:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkoyd (b) (4)	Query 1: Closed	Response satisfies query
Oct-12-2020 10:42:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-12-2020 10:42:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Temporal lobe Epilepsy	Transcription Error

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Oct-09-2020 22:46:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Please specify type of Epilepsy, if known. Thanks
Oct-08-2020 12:52:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Epilepsy	Initial Entry

**1.a Start Date:**

Date	Location	User	Value	Reason
Oct-08-2020 12:52:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2001	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Oct-08-2020 12:52:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Dec-01-2020 09:20:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Nu</b> 2 <b>mber:</b> <b>Medical Hist</b> Bilateral tubal liga <b>ory Term:</b> tion Sterilized <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> NO End Date:  UNK/UNK/201 8	Transcription Error
Oct-12-2020 10:34:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Nu</b> 2 <b>mber:</b> <b>Medical Hist</b> Bilateral tubal lig <b>ory Term:</b> ation Sterilized <b>Start Date:</b> UNK/UNK/2018	Transcription Error

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** GENERAL MEDICAL HISTORY - 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

			<b>Ongoing:</b> YES	
Oct-09-2020 07:52:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History:</b> Steralized <b>Term:</b> <b>Start Date:</b> UNK/UNK/2 018 <b>Ongoing:</b> YES	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Oct-09-2020 07:52:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Nov-03-2020 20:19:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-03-2020 14:03:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Test was not done at V1 in error
Nov-02-2020 22:43:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	GPD CLIN: Please clarify what information is to be updated. Thank you.
Nov-02-2020 14:18:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	To update once information is available
Oct-30-2020 10:03:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Since bilateral tubal ligation is not sufficient to confirm subject was not of childbearing potential, please clarify if there is any other information that may be added to the MH to confirm childbearing status (no preg test at visit 1).
Oct-29-2020 22:35:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLINQUERY: Since bilateral tubal ligation is not sufficient to confirm subject was not of childbearing

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

				potential, please clarify if there is any other information that may be added to the MH to confirm childbearing status (no preg test at visit 1).
Oct-12-2020 20:37:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 10:34:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-12-2020 10:34:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilateral tubal ligation Sterilized	Transcription Error
Oct-09-2020 18:05:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please update term to provide further detail (eg, bilateral tubal ligation, hysterectomy, etc). Thank you.
Oct-09-2020 07:52:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Steralized	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Oct-09-2020 07:52:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Dec-01-2020 18:13:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

Dec-01-2020 09:20:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-01-2020 09:20:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2018	Transcription Error
Nov-30-2020 19:25:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPD CLIN: Procedure should not be marked as ongoing, please update if appropriate. Thank you.
Nov-26-2020 09:39:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Procedure is not ongoing, however the result after the procedure is ongoing. Please clarify whether the procedure should be marked as ongoing or not.
Nov-26-2020 01:57:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLIN: Subject is noted to have had a surgical procedure of 'bilateral tubal ligation' which is noted as ongoing since 2018. Please confirm if event should be noted as ongoing. If not, please add stop date.
Oct-09-2020 07:52:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-08-2020 12:53:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Transcription Error
Oct-08-2020 12:52:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is 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: 12471220

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-08-2020 12:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/8/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-08-2020 12:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 109.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-08-2020 12:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-08-2020 12:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 164.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-08-2020 12:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-08-2020 12:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 40.5	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1247

Subject No: 12471220

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

7.a

Date	Location	User	Value	Reason
Oct-08-2020 12:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 37.0 <b>Temperature Unit:</b> C <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-08-2020 12:53:28 (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
Oct-08-2020 12:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-08-2020 12:53:28 (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
Oct-08-2020 12:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-08-2020 12:53:47 (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-08-2020 12:53:47 (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-08-2020 12:53:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/8/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-08-2020 12:53:47 (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-08-2020 12:53:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Oct-08-2020 12:53:47 (UTC+02:00) Harare,	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defin 113	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

Pretoria			<b>ed Identifier:</b>	
			<b>Test::</b>	Choriogonadotropin in Beta_PX113
			<b>Result::</b>	
			<b>Not Done::</b>	NOT DONE

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Oct-08-2020 12:53:47 (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-08-2020 12:53:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Oct-09-2020 23:15:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-09-2020 07:52:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	MedHx updated.
Oct-08-2020 20:16:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Subject is less than 60 years old and it is not clear from her medhx why a pregnancy test was not performed. Please review and update the MedHx log as appropriate else clarify. Thank you.

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

Oct-08-2020 12:53:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry
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**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-08-2020 12:54:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Oct/8/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-08-2020 12:54:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 104594	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: 12471220

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-08-2020 12:54:21 (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-08-2020 12:54:21 (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-08-2020 20:03:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-08-2020 16:09:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 12:54:21 (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-08-2020 12:54:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/8/2020	Initial Entry

5.a

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-08-2020 20:03:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BM9CV8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 20:03:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9CV8	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-08-2020 20:04:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRSTG2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 20:04:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSTG2	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-08-2020 20:04:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRSTG5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 20:04:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSTG5	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (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: 12471220

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-08-2020 12:54:34 (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-08-2020 12:54:34 (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-08-2020 20:03:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-08-2020 16:09:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 12:54:34 (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-08-2020 12:54:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/8/2020	Initial Entry

5.a

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (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:** 12471220

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Oct-08-2020 20:03:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM9CV2	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-08-2020 20:03:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9CV2	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471220

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

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-08-2020 12:54:58 (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-08-2020 12:54:58 (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-08-2020 12:54:58 (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 12:54:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/8/2020 09:38	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-08-2020 12:54:58 (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-08-2020 12:54:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471220

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

7. Route:

Date	Location	User	Value	Reason
Oct-08-2020 12:54:58 (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-08-2020 12:54:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION 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-08-2020 12:54:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

**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

[Back to Form](#)

*I. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Oct-19-2020 11:25:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Issue resolved. Subject is not subset of 'Reactogenicity Diary collection' now.
Oct-16-2020 14:25:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Email to be sent for CRA/Signant notification
Oct-15-2020 10:23:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data clarification sent.
Oct-14-2020 14:22:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per Trial Max, Subject is the subset of 'Reactogenicity Diary collection'. Please review and consider to update response for 'Reactogenicity diary collection' as 'Yes', else clarify in query response. Thanks.
Oct-08-2020 12:55:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-D IARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471220

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-28-2020 14:00:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/28/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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. Date:**

Date	Location	User	Value	Reason
Oct-28-2020 14:00:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/28/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-28-2020 14:00:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 37.0 <b>Temperature Unit:</b> C <b>Temperature Loca</b> ORAL CAV <b>tion::</b> ITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-28-2020 14:00:54 (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-28-2020 14:00:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 37.0	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-28-2020 14:00:54 (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
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090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** VITAL SIGNS - TEMP - 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-28-2020 14:00:54 (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: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-28-2020 14:01:13 (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-28-2020 14:01:13 (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-28-2020 14:01:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/28/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-28-2020 14:01:13 (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-28-2020 14:01:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Oct-28-2020 14:01:13 (UTC+02:00) Harare,	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defin 113	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

Pretoria			<b>ed Identifier:</b>	
			<b>Test::</b>	Choriogonadotropin Beta_PX113
			<b>Result::</b>	NEGATIVE
			<b>Not Done::</b>	

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Oct-28-2020 14:01:13 (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-28-2020 14:01:13 (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-28-2020 14:01:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (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: 12471220

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-28-2020 14:01:33 (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-28-2020 14:01:33 (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-29-2020 10:06:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 14:01:33 (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-28-2020 14:01:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> YES Date of Collection:  Oct/28/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-29-2020 10:06:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Sample ID: BM9FKT	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (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:** 12471220

**Subject Initials:** ---

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

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

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-29-2020 10:06:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> BM9FKT	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471220

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

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-28-2020 14:01:50 (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-28-2020 14:01:50 (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-28-2020 14:01:50 (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-28-2020 14:01:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/28/2020 11:09	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-28-2020 14:01:50 (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-28-2020 14:01:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471220

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

**7. Route:**

Date	Location	User	Value	Reason
Oct-28-2020 14:01:50 (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-28-2020 14:01:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION 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-28-2020 14:01:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** DATE OF VISIT - 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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-30-2020 10:40:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/30/2020	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471220

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
Nov-30-2020 10:41:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-30-2020 10:41:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-01-2020 08:28:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2 : Closed	Response satisfies query
Nov-30-2020 21:07:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Closed	Close Auto Query
Nov-30-2020 21:07:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2 : Answered	Transcription Error
Nov-30-2020 21:07:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/	Transcription Error

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

			30/2020	
Nov-30-2020 16:32:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2 : Opened	DMW6273907;Date of Collection is not equal to Date of Visit. Please clarify or correct.
Nov-30-2020 12:11:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-30-2020 10:41:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-30-2020 10:41:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/23/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-30-2020 21:07:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR7MSB	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-30-2020 21:07:32 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR7MSB	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

Pretoria		(b) (4), (b) (6)	
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5.b

Date	Location	User	Value	Reason
Nov-30-2020 21:07:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRY9S5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-30-2020 21:07:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRY9S5	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-30-2020 21:07:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRY9S6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-30-2020 21:07:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRY9S6	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Dec/24/2020

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: 12471220

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
Dec-24-2020 13:58:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-24-2020 13:56:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-24-2020 13:56:28 (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.
Dec-24-2020 13:56:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/24/2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-24-2020 13:56:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020**Form Version:** 10-Dec-2020 02:29**Site No:** 1247**Subject No:** 12471220**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/24/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/22/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Dec-29-2020 11:21:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved: Dec/26/2020	New Information
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

Pretoria		(b) (4), (b) (6)	
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4.a Was symptom present?

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom P present:</b> NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (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
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471220**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**4.c Symptoms:**

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTN ESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

**4.d Symptoms:**

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (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
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREAS <b>s:</b> ED MUSCLE PAIN	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

			Symptom Present:	NO
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4.e Symptoms:

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms : NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (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
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.g

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (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
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (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
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

4.i

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-24-2020 13:57:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/24/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

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
Dec-24-2020 13:57:33 (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
Dec-24-2020 13:57:33 (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
Dec-24-2020 13:57:33 (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
Dec-24-2020 13:57:33 (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
Dec-24-2020 13:57:33 (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
Dec-24-2020 13:57:33 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

Pretoria		(b) (4), (b) (6)	
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**7. Test Result:**

Date	Location	User	Value	Reason
Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Dec-24-2020 13:57:33 (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
Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Dec/24/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1247**Subject No:** 12471220**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -  
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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-24-2020 13:58:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-24-2020 13:58:07 (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
Dec-24-2020 13:58:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-24-2020 13:58:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-24-2020 13:58:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/24/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-24-2020 13:58:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: CV48884	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**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:** 12471220

**Subject Initials:** ---

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

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-24-2020 13:58:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CV48884	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**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:** 12471220

**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
Dec-24-2020 13:58:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-24-2020 13:58:43 (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
Dec-24-2020 13:58:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Dec-24-2020 13:58:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Self-swab collected	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/24/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (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
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/24/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471220**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN N <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/24/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

Dec-24-2020 13:59:06 (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</b> NO <b>or Contacts:</b>	Initial Entry
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***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (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
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (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> NO	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/24/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471220**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (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
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH ER <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***3. Has the subject been hospitalized due to potential COVID-19 illness?***

Date	Location	User	Value	Reason
Dec-24-2020 13:59:06 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

Pretoria	(b) (4), (b) (6)
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Dec/24/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

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
Dec-24-2020 14:00:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Dec-24-2020 14:00:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Dec-24-2020 14:00:36 (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
Dec-24-2020 14:00:36 (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
Dec-24-2020 14:00:36 (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
Dec-24-2020 14:00:36 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History  
on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

Pretoria	(b) (4), (b) (6)
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Dec/24/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-24-2020 13:59:49 (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
Dec-24-2020 13:59:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Pharyngitis  Date of Diagnosis:  Dec/24/2020	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-24-2020 13:59:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Dec/24/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-24-2020 14:00:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Dec-24-2020 14:00:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Dec-24-2020 14:00:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-24-2020 14:00:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

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.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

(UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	<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
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (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
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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Form Version: 15-Sep-2020 21:51

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (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
Dec-24-2020 14:01:45 (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
Dec-24-2020 14:01:45 (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
Dec-24-2020 14:01:45 (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
Dec-24-2020 14:01:45 (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

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

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.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (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
Dec-24-2020 14:01:45 (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
Dec-24-2020 14:01:45 (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
Dec-24-2020 14:01:45 (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
Dec-24-2020 14:01:45 (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
Dec-24-2020 14:01:45	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

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

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

(UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	<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

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
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			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

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			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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Form Version: 15-Sep-2020 21:55

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Site No: 1247

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Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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**Subject No:** 12471220

**Subject Initials:** ---

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

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

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			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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Subject No: 12471220

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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
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
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			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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Form Version: 15-Sep-2020 21:55

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

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5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

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

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

			<b>Test::</b>	Not Done
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			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

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

[Back to Form](#)

**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Test:**

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**5.i Result:**

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Dec-24-2020 14:01:45 (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
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**5.i LNMT**

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (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
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Not Done	Initial Entry

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

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Header Text: c4591001

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5.j Sponsor ID:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Dec-24-2020 14:01:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Dec/24/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**I. Date:**

Date	Location	User	Value	Reason
Dec-24-2020 14:02:19 (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
Dec-24-2020 14:02:19 (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
Dec-24-2020 14:02:19 (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
Dec-24-2020 14:02:19 (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
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090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
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**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

Dec-24-2020 14:02:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Dec-24-2020 14:02:19 (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
Dec-24-2020 14:02:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**I. Date:**

Date	Location	User	Value	Reason
Dec-24-2020 14:02:41 (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
Dec-24-2020 14:02:41 (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
Dec-24-2020 14:02:41 (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
Dec-24-2020 14:02:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Dec/24/2020

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Dec-24-2020 14:03:18 (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
Dec-24-2020 14:03:18 (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
Dec-24-2020 14:03:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

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
Dec-24-2020 14:03:57 (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
Dec-24-2020 14:03:57 (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
Dec-24-2020 14:03:57 (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
Dec-24-2020 14:03:57 (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
Dec-24-2020 14:03:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6. Ongoing?

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/24/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Dec-24-2020 14:03:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Dec/24/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

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
Dec-24-2020 14:04:20 (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
Dec-24-2020 14:04:20 (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
Dec-24-2020 14:04:20 (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
Dec-24-2020 14:04:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Jan/21/2021

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit  
Trail History

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

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

**Site No:** 1247

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

**Subject No:** 12471220

**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
Jan-22-2021 14:07:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/21/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 14:07:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Jan/21/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1247**Subject No:** 12471220**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-22-2021 14:07:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-22-2021 14:07:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-22-2021 14:16:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-22-2021 14:07:30 (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.
Jan-22-2021 14:07:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/21/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-22-2021 14:16:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR7MTD	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Jan/21/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 14:16:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR7MTD	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-22-2021 14:22:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRY9VT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 14:22:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRY9VT	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-22-2021 14:22:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRY9VV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-22-2021 14:22:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRY9VV	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/30/2020

**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:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-02-2020 13:37:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/30/2020

**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:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

**I. Assessments**

Date	Location	User	Value	Reason
Nov-02-2020 13:38:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-02-2020 13:37:37 (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.
Nov-02-2020 13:37:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/30/2020

**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:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Contact Type:**

Date	Location	User	Value	Reason
Nov-02-2020 13:38:28 (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
Nov-02-2020 13:38:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Oct/30/2020  Contact Outcome:  VISIT NOT REQUIRED, DAT A ENTRY ERROR IN E-DIAR Y	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

**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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-30-2020 10:43:39 (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:** 12471220

**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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-30-2020 10:44:40 (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:** 12471220

**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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-30-2020 10:45:24 (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:** 12471220

**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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-30-2020 10:46:38 (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:** 12471220

**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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-30-2020 10:47:33 (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: 12471220

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-30-2020 10:43:39 (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-30-2020 10:43:39 (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-30-2020 10:43:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Diarrhea	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-30-2020 10:43:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-30-2020 10:43:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Oct/10/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

Nov-30-2020 10:43:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-30-2020 10:43:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-30-2020 10:43:39 (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-30-2020 10:43:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-30-2020 10:43:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-30-2020 10:43:39 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

Pretoria		(b) (4), (b) (6)		
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-30-2020 10:43:39 (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-30-2020 10:43:39 (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-30-2020 10:43:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:40 (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-30-2020 10:44:40 (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-30-2020 10:44:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Headaches	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/29/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Oct/29/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

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Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

Nov-30-2020 10:44:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-30-2020 10:44:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-30-2020 10:44:40 (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-30-2020 10:44:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-30-2020 10:44:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-30-2020 10:44:40 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

Pretoria		(b) (4), (b) (6)		
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-30-2020 10:44:40 (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-30-2020 10:44:40 (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-30-2020 10:44:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-30-2020 10:45:24 (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-30-2020 10:45:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-01-2020 18:20:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-01-2020 10:18:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-01-2020 10:18:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Generalized Joint pain	New Information
Nov-30-2020 20:23:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please update the CRF to specify anatomical site in the event term. If generalized, please state as such. Thank you.
Nov-30-2020 10:45:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Joint pain	Initial Entry

**4. Start Date Time:**

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Nov-30-2020 10:45:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-30-2020 10:45:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Oct/29/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-30-2020 10:45:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-30-2020 10:45:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-30-2020 10:45:24 (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:

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Nov-30-2020 10:45:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-30-2020 10:45:24 (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-30-2020 10:45:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-30-2020 10:45:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Nov-30-2020 10:45:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Nov-30-2020 10:45:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-30-2020 10:46:38 (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-30-2020 10:46:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-30-2020 10:46:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Left axillary lymphadenopathy	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-30-2020 10:46:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/29/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-30-2020 10:46:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Nov/2/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

Nov-30-2020 10:46:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-30-2020 10:46:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-30-2020 10:46:38 (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-30-2020 10:46:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-30-2020 10:46:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-30-2020 10:46:38 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

Pretoria		(b) (4), (b) (6)		
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-30-2020 10:46:38 (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-30-2020 10:46:38 (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-30-2020 10:46:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-30-2020 10:47:33 (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-30-2020 10:47:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Dec-02-2020 20:47:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-02-2020 08:16:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	No- related to vaccine
Dec-01-2020 18:22:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	GPD CLIN: Please confirm if AE of ongoing Grade 2 'joint pain' could be related to COVID-19. If confirmed, please conduct a COVID illness visit and swab collection as soon as possible and capture term on SOD form only. Please review and update.
Dec-01-2020 18:21:23 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1247**Subject No:** 12471220**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

Pretoria				
Dec-01-2020 10:18:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-01-2020 10:18:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-01-2020 10:18:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Generalized Joint pain	New Information
Nov-30-2020 20:39:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	GPD CLIN: Please confirm if AE of ongoing Grade 2 'joint pain' could be related to COVID-19. If confirmed, please conduct a COVID illness visit and swab collection as soon as possible and capture term on SOD form only. Please review and update.
Nov-30-2020 20:23:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CLINQUERY: Please update the CRF to specify anatomical site in the event term. If generalized, please state as such. Thank you.
Nov-30-2020 10:47:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Joint pain	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-30-2020 10:47:33 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Oct/30/2020 UNK:UNK	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

Pretoria		(pfe.tpeters)	
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-27-2021 23:11:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Jan-27-2021 11:19:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Confirmed still ongoing
Jan-25-2021 17:25:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Please review if event remains ongoing. Else, report end date and update event outcome status
Dec-09-2020 18:15:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Dec-03-2020 07:49:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ongoing at this stage - patient is being follow up by GP and will forward results as soon as they are available
Dec-02-2020 14:43:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please confirm if this AE is still ongoing?
Nov-30-2020 10:47:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-30-2020 10:47:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

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-30-2020 10:47:33 (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-30-2020 10:47:33 (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-30-2020 10:47:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-30-2020 10:47:33 (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-30-2020 10:47:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

Nov-30-2020 10:47:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Nov-30-2020 10:47:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Nov-30-2020 10:47:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: MEDICATION ERROR - 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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Dec-01-2020 13:17:24 (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
Dec-01-2020 13:17:24 (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
Dec-01-2020 13:17:24 (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
Dec-01-2020 13:17:24 (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
Dec-01-2020 13:17:24 (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
Dec-01-2020 13:17:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471220

Generated By: (b) (4)

Form: MEDICATION ERROR - 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

**7. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Dec-01-2020 13:17:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Did the Medication Error cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Dec-01-2020 13:17:24 (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
Dec-01-2020 13:17:24 (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
Dec-01-2020 13:17:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471220

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
Dec-01-2020 13:17:55 (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
Dec-01-2020 13:17:55 (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
Dec-01-2020 13:17:55 (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
Dec-01-2020 13:17:55 (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
Dec-01-2020 13:17:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471220

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
Dec-01-2020 13:18:26 (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
Dec-01-2020 13:18:26 (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
Dec-01-2020 13:18:26 (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
Dec-01-2020 13:18:26 (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
Dec-01-2020 13:18:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Dose Unit:**

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471220

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-01-2020 13:18:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**7. Dose Frequency:**

Date	Location	User	Value	Reason
Dec-01-2020 13:18:26 (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
Dec-01-2020 13:18:26 (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
Dec-01-2020 13:18:26 (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
Dec-01-2020 13:18:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471220

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Dec-01-2020 13:18:44 (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
Dec-01-2020 13:18:44 (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
Dec-01-2020 13:18:44 (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
Dec-01-2020 13:18:44 (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
Dec-01-2020 13:18:44 (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
Dec-01-2020 13:18:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

**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

[Back to Form](#)

**1. Transfusion Type:**

Date	Location	User	Value	Reason
Dec-01-2020 13:19:01 (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
Dec-01-2020 13:19:01 (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 Version:** 15-Sep-2020 21:55

**Site No:** 1247

**Subject No:** 12471220

**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

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-30-2020 10:41:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-30-2020 10:41:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-30-2020 10:41:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1247

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

**Subject No:** 12471220

**Subject Initials:** ---

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

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-23-2021 13:32:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/27/2021	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail  
History

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-24-2021 16:55:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible and NOT confirme d to have received only pla cebo at Vaccination 1/2	Changed Information
Feb-23-2021 13:32:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Participant is NOT willing to r eturn for Vaccination 3 OR oth erwise not eligible	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471220

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

[Back to Form](#)

**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-23-2021 13:33:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/27/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-24-2021 21:45:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Clo sed	Response satisfies query
Feb-24-2021 16:55:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	"Participant is willing to return" is selected
Feb-24-2021 12:34:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7399252;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Feb-23-2021 13:33:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : ASSE SS EL IGIBI LITY	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

**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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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** WITHDRAWAL OF CONSENT - 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

[Back to Form](#)

**I. Withdrawal of Consent Date :**

Date	Location	User	Value	Reason
Feb-23-2021 13:33:42 (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:** 12471220

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

**Form:** DEATH DETAILS CODED - 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

[Back to Form](#)

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

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-23-2021 13:34:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** SUBJECT STATUS - 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

[Back to Form](#)

**1. Subject Status**

Date	Location	User	Value	Reason
Nov-30-2020 10:41:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-08-2020 12:54:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-08-2020 12:51:55 (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
Nov-30-2020 10:41:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/30/2020	Initial Entry
Oct-08-2020 12:54:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/8/2020	Initial Entry
Oct-08-2020 12:51:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/8/2020	Initial Entry

090177e196ae2fc2\Final\Final On: 01-Apr-2021 03:51 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471220

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

**Form:** CASEBOOK SIGNATURE FORM - 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

[Back to Form](#)

*1. Casebook Signature*

Date	Location	User	Value	Reason
Nov-11-2020 11:35:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry