

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** COHORT\_SELECTION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** MAIN INFORMED CONSENT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/28/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** DEMOGRAPHY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12471066]
2.	Birth Date:	UNK/UNK/1962
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

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**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** DISPOSITION - SCREENING

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/28/2020
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:** 12471066

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Post Menopausal]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bilateral tubal ligation]
	Start Date:	UNK/UNK/1997
	Ongoing:	NO End Date: UNK/UNK/1997

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**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** HIV STATUS

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**HIV Status**

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



**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VITAL SIGNS - BASELINE

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/28/2020
2.	Weight:	[95.0]
3.	Unit:	kg
4.	Height:	[160.0]
5.	Unit:	cm
6.	Body Mass Index:	[37.1]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.1]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/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:	
	Not Done:	NOT DONE

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** RANDOMIZATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/29/2020
2.	Randomization Number:	[266464]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/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	[BM9CHB]
5.b	Sample ID	[BRSDYF]
5.c	Sample ID	[BRSDYG]

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**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/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	[BM9CH6]
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**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/29/2020 08:56
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** REACTOGENICITY DIARY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

**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/20/2020
2.	Erroneous Visit	



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471066

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vital Signs**

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

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	Temperature:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Unit:	Not Applicable _____ _____	<a href="#">Comments</a>
	Temperature Location:	Not Applicable _____ _____	<a href="#">Comments</a>

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471066

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

**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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE	<a href="#">Comments</a>
2.	Sample Type	NASAL_SWAB	<a href="#">Comments</a>
3.	Sample Collected?	NO	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Patient not receiving Vax 2 after positive swab test]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471066

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	Not Applicable _____	<a href="#">Comments</a>
2.	Treatment Name	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Formulation:	Not Applicable _____	<a href="#">Comments</a>
4.	Dose Date Time:	Not Applicable _____ //	<a href="#">Comments</a>
5.	Anatomical Location:	Not Applicable _____	<a href="#">Comments</a>
6.	Body Side:	Not Applicable _____	<a href="#">Comments</a>
7.	Route:	Not Applicable _____	<a href="#">Comments</a>
8.	Actual Dose:	Not Applicable _____ [ ]	<a href="#">Comments</a>
9.	Unit:	Not Applicable _____	<a href="#">Comments</a>
10.	Timeframe Subject Was Observed	Not Applicable _____	<a href="#">Comments</a>
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

**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	Nov/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Convalescent visit and Visit 3 occurred on same day. Samples collected captured at convalescent visit]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	Not Done _____ [ ]	<a href="#">Comments</a>
5.b	Sample ID	Not Done _____ [ ]	<a href="#">Comments</a>
5.c	Sample ID	Not Done _____ [ ]	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1247

**Subject No:** 12471066

**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:** 12471066

**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:** 12471066

**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:** 12471066

**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:** 12471066

**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:** 12471066

**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 on **Form:** DATE OF VISIT - ILLNESS ONSET  
Oct/16/2020

**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:** 12471066

**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/16/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Oct/16/2020
2.	Date of First Symptom Started:	Oct/15/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/27/2020

**Symptoms**

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

**Symptoms - Other**

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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:** 12471066

**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. DELETED		SWABBED MATERIAL	NASOPHARYNX			<a href="#">Repeating Pages</a>
2.	Oct/23/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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

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[eCRF Audit Trail History](#)  
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**Microbiology Specimen**

1.	Actual Date of Collection:	//
2.	Specimen Type:	<del>SWABBED MATERIAL</del>
3.	Specimen Collection Location:	<del>NASOPHARYNX</del>
4.	Assay Code and Description:	
5.	Device Type:	
6.	Trade Name:	
7.	Test Result:	<del>NEGATIVE</del>
8.	Comments/Findings/Details:	[details of swab will be confirmed]
9.	Trade Name Other, Specify:	[ ]

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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**Microbiology Specimen**

1.	Actual Date of Collection:	Oct/23/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	POSITIVE
8.	Comments/Findings/Details:	[Covid Illness confirmed by positive SARS_CoV_2 PCR test done at the National Health Laboratory Services in Cape Town South Africa]
9.	Trade Name Other, Specify:	[CLIA-certified lab]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF  
Oct/16/2020

**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:** 12471066

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Oct/16/2020
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	[CV23918]
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090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
Oct/16/2020

**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:** 12471066

**Subject Initials:** ---

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

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

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**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 performed]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION  
Oct/16/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471066**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:	YES Number of Visits or Contacts: [1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [7]
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
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**Health Care Utilization**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** HOSPITALIZATION DETAILS

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

**Subject Initials:** ---

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Oct/23/2020	NO Discharge Date:  Oct/26/2020	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Oct/23/2020
4.	Ongoing?	NO Discharge Date: Oct/26/2020

**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:** 12471066

**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.	1	YES	HIGH FLOW OXYGEN THERAPY	HIGH FLOW OXYGEN THERAPY	Oct/23/2020	<a href="#">Repeating Pages</a>

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT  
Oct/16/2020

**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:** 12471066

**Subject Initials:** ---

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

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

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**Respiratory Treatment**

1.	What is the treatment Identifier?	[1]	<a href="#">Comments</a>
2.	Concomitant Non-drug Treatment Pre-specified:	YES	<a href="#">Comments</a>
3.	Treatment:	HIGH FLOW OXYGEN THERAPY	<a href="#">Comments</a>
4.	Treatment:	[HIGH FLOW OXYGEN THERAPY]	<a href="#">Comments</a>
5.	Start Date:	Oct/23/2020	<a href="#">Comments</a>
6.	Ongoing?	NO End Date: Oct/24/2020	<a href="#">Comments</a>

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [COVID-19]  Date of Diagnosis: Oct/23/2020
3.	Toxicity Grade:	3

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**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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**Illness Details**

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

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1247

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

Subject No: 12471066

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

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Oct/16/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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**Lab Chemistry Details**

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

**Lab Result**

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

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Oct/16/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Oct/16/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Oct/16/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1247

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

Subject No: 12471066

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

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology Oct/16/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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**Laboratory Data Hematology**

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

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
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**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
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**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology  
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Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology  
Oct/16/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 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:** 12471066

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 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:** 12471066

**Subject Initials:** ---

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

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

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

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

**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:** 12471066

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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**Oxygenation Parameters**

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

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**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1247

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

**Subject No:** 12471066

**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:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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**Concomitant Medications**

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

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**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1247

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

**Subject No:** 12471066

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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**Imaging**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/16/2020

**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:** 12471066

**Subject Initials:** ---

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

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

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**Date of Visit**

1.	Date of Visit	Nov/16/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/16/2020

**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:** 12471066

**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: Nov/16/2020
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	[BM9FR7]
5.b	Sample ID	[BRSTMD]
5.c	Sample ID	[BRSTMF]

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**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:** 12471066

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**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:** 12471066

**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 - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

**Unplanned Assessments**

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

**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:** 12471066

**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 On going	Form Instance
1. DELETED	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: 12471066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

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

Subject Initials: ---

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

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

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**Adverse Event Report**

1.	Category:	Not Applicable _____	<a href="#">Comments</a>
2.	AE ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	Not Applicable _____ [ ]	<a href="#">Comments</a>
4.	Start Date Time:	Not Applicable _____ //	<a href="#">Comments</a>
5.	Is the adverse event still ongoing?	Not Applicable _____	<a href="#">Comments</a>
6.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>
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).	Not Applicable _____	<a href="#">Comments</a>
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.	Not Applicable _____	<a href="#">Comments</a>
9.	Is this event related to study treatment:	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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

10.	Latest Action Taken with Study Treatment:	Not Applicable _____	<a href="#">Comments</a>
11.	Was a Concomitant Medication given?	Not Applicable _____	<a href="#">Comments</a>
12.	Was a Non-Drug Treatment given?	Not Applicable _____	<a href="#">Comments</a>
13.	What was the outcome of this adverse event?:	Not Applicable _____	<a href="#">Comments</a>
14.	Did the adverse event cause the subject to be discontinued from the study?	Not Applicable _____	<a href="#">Comments</a>
15.	Serious Adverse Event Number: For Pfizer Use Only	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1247

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

**Subject No:** 12471066

**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:** 12471066

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

**Form:** MEDICATION ERROR

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

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

**Subject Initials:** ---

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

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**Medication Error**

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

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (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:** 12471066

**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:** 12471066

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

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

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

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

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1247

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

**Subject No:** 12471066

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

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

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

**Subject Initials:** ---

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

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

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]	<a href="#">Comments</a>
2.	Category:		<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:		<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).	[ ]	<a href="#">Comments</a>
5.	Dose:	[ ]	<a href="#">Comments</a>
6.	Dose Unit:		<a href="#">Comments</a>
7.	Dose Frequency:		<a href="#">Comments</a>
8.	Route:		<a href="#">Comments</a>
9.	Start Date:	//	<a href="#">Comments</a>
10.	Ongoing?		<a href="#">Comments</a>

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (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:** 12471066

**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>

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** RADIATION TREATMENT

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

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

**Subject Initials:** ---

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

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**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>

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (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:** 12471066

**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>

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** TRANSFUSIONS

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

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

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** DISPOSITION - TREATMENT

**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 - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/15/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	NO LONGER MEETS ELIGIBILITY CRITERIA
4.	Specify Status:	[Patient tested positive for COVID 19 and was symptomatic prior to visit 2]

**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:** 12471066

**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:** 12471066

**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:** 12471066

**Subject Initials:** ---

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

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

**Lab Urinalysis**

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

**Lab Result**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1247

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

**Subject No:** 12471066

**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?	

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (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:** 12471066

**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:** 12471066

**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:** 12471066

**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:** 12471066

**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:** 12471066

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1247

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

**Subject No:** 12471066

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

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471066

**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:** 12471066

**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	Feb/5/2021
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:** 12471066

**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 per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471066

**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 :	Feb/8/2021
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:** 12471066

**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**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471066

**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 _____ [ ]

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1247

**Subject No:** 12471066

**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:** V101\_VAX3

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Informed Consent - Further Vaccination**

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

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

**Form Status:** Not Started

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	
----	---	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1247

**Subject No:** 12471066

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

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

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Disposition - Screening for Further Vaccination**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471066

**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	DISCONTINUED
2.	Subject Status Date	Oct/15/2020



**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:** 12471066

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

**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:** 12471066

**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
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**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

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

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Sep-28-2020 14:34:35 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VITAL SIGNS - TEMP - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Nov-11-2020 08:16:06 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receiving Vax2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VITAL SIGNS - TEMP - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Nov-11-2020 08:16:06 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient not receiving Vax2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VITAL SIGNS - TEMP - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2.a	Nov-11-2020 08:16:06 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receiving Vax2
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VITAL SIGNS - TEMP - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2.a	Nov-11-2020 08:16:06 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient not receiving Vax2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**Site No:** 1247

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

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

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Item	Date	User	Comment
2.a	Nov-11-2020 08:16:06 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient not receiving Vax2 Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receivng Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient not receivng Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient not receivng Vax 2 Not Applicable

**Header Text:** c4591001

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**Site No:** 1247

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**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient not receivng Vax 2 Not Applicable

**Header Text:** c4591001

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**Site No:** 1247

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**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
4	Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient not receivng Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5	Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receivng Vax 2
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receivng Vax 2
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receivng Vax 2
			Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

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

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Item	Date	User	Comment
6.a	Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient not receivng Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**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:** 12471066

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Nov-13-2020 07:32:10 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
Form	Nov-11-2020 08:17:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**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:** 12471066

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
1	Nov-13-2020 07:32:10 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
1	Nov-11-2020 08:17:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**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:** 12471066

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2	Nov-13-2020 07:32:10 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
2	Nov-11-2020 08:17:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**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:** 12471066

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
3	Nov-13-2020 07:32:10 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
3	Nov-11-2020 08:17:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**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:** 12471066

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
4	Nov-13-2020 07:32:10 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
4	Nov-11-2020 08:17:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient not receiving Vax 2 Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION - Comments

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

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

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Item	Date	User	Comment
4	Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receiving Vax 2 Not Applicable
4	Oct-29-2020 07:43:06 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	This visit is delayed due to the use corticosteroids.

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5	Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6	Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
7	Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
8	Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
9	Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receiving Vax 2
			Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
10	Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient not receiving Vax 2 Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** VACCINATION - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
11	Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient not receiving Vax 2
			Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
1	Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2.a	Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1247

**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

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Item	Date	User	Comment
2.b	Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1247

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

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

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

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Item	Date	User	Comment
2.c	Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

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

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

**Site No:** 1247

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

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Item	Date	User	Comment
2.d	Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

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

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

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2.e	Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

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Item	Date	User	Comment
2 f	Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
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**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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Item	Date	User	Comment
5.a	Feb-12-2021 07:32:16 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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**Subject No:** 12471066

**Subject Initials:** ---

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

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

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

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**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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Item	Date	User	Comment
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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments  
Oct/16/2020

**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:** 12471066

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Mar-08-2021 15:08:31 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
Form	Oct-20-2020 16:34:21 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

**Header Text:** c4591001

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Oct/16/2020

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

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

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Item	Date	User	Comment
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1	Oct-20-2020 16:34:21 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

**Header Text:** c4591001

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Oct/16/2020

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
5	Mar-08-2021 15:08:31 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
5	Oct-20-2020 16:34:21 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

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Oct/16/2020

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Item	Date	User	Comment
6	Mar-08-2021 15:08:31 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
6	Oct-20-2020 16:34:21 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

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

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

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Item	Date	User	Comment
Form	Oct-24-2020 10:51:10 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable
Form	Oct-24-2020 10:48:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
Form	Oct-20-2020 16:36:58 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments  
Oct/16/2020

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Item	Date	User	Comment
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Item	Date	User	Comment
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**Subject No:** 12471066

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Oct-20-2020 16:38:23 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

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

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

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Item	Date	User	Comment
1	Oct-20-2020 16:38:23 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments  
Oct/16/2020

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

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

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Item	Date	User	Comment
2.a	Oct-20-2020 16:38:23 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Comments  
Oct/16/2020

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Oct-20-2020 16:38:38 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Comments  
Oct/16/2020

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

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Item	Date	User	Comment
1	Oct-20-2020 16:38:38 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
3	Oct-20-2020 16:38:38 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
Oct/16/2020

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

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

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Item	Date	User	Comment
Form	Oct-20-2020 16:39:05 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
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Item	Date	User	Comment
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Item	Date	User	Comment
Form	Oct-20-2020 16:39:48 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
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**Form Version:** 22-Apr-2020 21:02

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** ADVERSE EVENT REPORT - Comments

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

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

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

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Item	Date	User	Comment
Form	Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1247

**Subject No:** 12471066

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**Form:** ADVERSE EVENT REPORT - Comments

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

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Item	Date	User	Comment
1	Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
5	Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
6	Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
7	Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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

**Site No:** 1247

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**Form:** ADVERSE EVENT REPORT - Comments

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

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Item	Date	User	Comment
8	Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

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Item	Date	User	Comment
9	Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
15	Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

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

**Site No:** 1247

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**Form:** MEDICATION ERROR - Comments

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Item	Date	User	Comment
Form	Oct-23-2020 08:29:14 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

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**Header Text:** c4591001

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

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**Subject No:** 12471066

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

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

**Subject Initials:** ---

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

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VACCINATIONS - Comments

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

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Form	Feb-22-2021 15:34:36 (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:** 12471066

**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

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Item	Date	User	Comment
1	Feb-22-2021 15:34:36 (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:** 12471066

**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

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Item	Date	User	Comment
Form	Feb-22-2021 15:34:59 (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:** 12471066

**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

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Item	Date	User	Comment
1	Feb-22-2021 15:34:59 (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:** 12471066

**Subject Initials:** ---

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

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

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-06-2021 09:53:02 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated

**Affidavit:**

N/A

Haylene Nell	Approved	Jan-27-2021 16:06:32 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Dec-17-2020 14:35:40 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Haylene Nell	Approved	Dec-02-2020 09:32:35 (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.

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Data Complete, Verified

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

(b) (6)	N/A	Dec-01-2020 09:12:05 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Haylene Nell	Approved	Nov-17-2020 08:44:11 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-13-2020 07:32:10 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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**Affidavit:**

N/A

Haylene Nell	Approved	Nov-12-2020 14:02:45 (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.

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** COHORT SELECTION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-28-2020 10:13:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:13:56 (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:** 12471066

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

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Consent Was:*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-28-2020 10:14:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/28/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1247

Subject No: 12471066

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-28-2020 10:13:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12471066	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-28-2020 10:13:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> UNK/UNK/1962	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-28-2020 10:14:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-28-2020 10:14:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:14:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLACK OR AFRICAN AMERICA N	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-28-2020 14:34:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:52

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Sep-28-2020 14:34:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-28-2020 14:34:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-28-2020 14:34:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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*I.a*

Date	Location	User	Value	Reason
Sep-28-2020 16:41:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number</b> 1 : <b>Medical History Term:</b> Post Menopausal <b>Start Date:</b> UNK/UNK/2019 <b>Ongoing:</b> YES	Transcription Error
Sep-28-2020 14:35:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 1 : <b>Medical History Term:</b> Post Menopausal <b>Start Date:</b> UNK/UNK/2019 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-28-2020 14:35:20 (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
Nov-06-2020 17:16:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-06-2020 17:16:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-06-2020 09:46:26	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	PD noted. Bilateral tubal ligation

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)		added to medical history
Nov-06-2020 09:19:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Noted
Nov-04-2020 20:48:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	GPD CLIN: Please add bilateral tubal ligation to the medical history. Thank you.
Nov-04-2020 20:45:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	GPD CLIN: Bilateral tubal ligation does not meet the criteria for non child bearing potential. Protocol deviation will be noted for not having been completed at visit 1. Please ensure pregnancy test is done prior to vac#2. Thank you.
Nov-04-2020 10:37:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	No patient also had a bilateral tubal ligation
Nov-02-2020 23:36:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	GPD CLIN: Please confirm subject met protocol definition of postmenopausal (see section 10.4.3), no menses for 12 months and high FSH level if not using hormonal contraception or HRT. Thank you.
Nov-02-2020 22:20:12 (UTC+02:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	GPD CLIN: Please confirm subject met protocol

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** GENERAL MEDICAL HISTORY - 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

Harare, Pretoria				definition of postmenopausal (see section 10.4.3), no menses for 12 months and high FSH level if not using hormonal contraception or HRT. Thank you.
Sep-28-2020 18:26:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-28-2020 16:41:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-28-2020 16:41:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Post Menopausal	Transcription Error
Sep-28-2020 16:00:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify POST MENOPAUSEL as follows...Should the spelling be POST MENOPAUSAL? If so, edit. Otherwise clarify. Thank you.
Sep-28-2020 14:35:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Post Menopausal	Initial Entry

***1.a Start Date:***

Date	Location	User	Value	Reason
Sep-28-2020 14:35:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

***1.a Ongoing:***

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-28-2020 14:35:20 (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 09:12:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> Bilateral tubal ligation <b>Start Date:</b> UNK/UNK/1997 <b>Ongoing:</b> NO End Date: UNK/UNK/1997	Transcription Error
Nov-06-2020 09:45:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> Bilateral tubal ligation <b>Start Date:</b> UNK/UNK/1997 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Nov-06-2020 09:45:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Nov-06-2020 09:45:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilateral tubal ligation	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Nov-06-2020 09:45:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1997	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Dec-01-2020 18:09:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-01-2020 09:12:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-01-2020 09:12:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/1997	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 09:32:18 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Procedure is not ongoing, however

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** GENERAL MEDICAL HISTORY - 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

Pretoria		(b) (4), (b) (6)		the result after the procedure is ongoing. Please clarify whether the procedure should be marked as ongoing or not.
Nov-26-2020 01:52:58 (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 1997. Please confirm if event should be noted as ongoing. If not, please add stop date.
Nov-06-2020 09:45:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** HIV STATUS - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-28-2020 14:36:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HI V POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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*I. Date:*

Date	Location	User	Value	Reason
Oct-16-2020 16:27:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-15-2020 09:54:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Pt. only had vaccination done. Vitals were done on consent day.
Oct-14-2020 09:54:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM 1: All V1 assessments are expected to be reported when subject returns for Vaccination on 29/Sep/2020. Thus, Please review and explain why Vitals signs was not repeated on the vaccination day. If repeated, please review and update . Else, clarify.
Oct-13-2020 09:29:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Vaccination delay due to temperature excursion. Original value of vital signs correct.
Oct-12-2020 16:40:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Vital Signs Date is not the same as Vaccination Date in the same visit. Please review and update as appropriate or clarify.
Sep-28-2020 14:37:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1247

Subject No: 12471066

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

2. Weight:

Date	Location	User	Value	Reason
Sep-28-2020 14:37:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 95.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-28-2020 14:37:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-28-2020 14:37:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 160.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-28-2020 14:37:20 (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
Sep-28-2020 14:37:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 37.1	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-28-2020 14:37:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 36.1 Temperature Unit: C Temperature Locat ion:: ORAL CAVI TY	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1247

Subject No: 12471066

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 Record Identifier:

Date	Location	User	Value	Reason
Sep-28-2020 14:37:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-28-2020 14:37:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 36.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-28-2020 14:37:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-28-2020 14:37:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (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: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-28-2020 14:37:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-28-2020 14:37:38 (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-01-2020 09:40:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed per SITE response, added to PD tracker
Oct-01-2020 07:31:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Patient came next day due to temperature excursion on 28 Sep 2020
Sep-30-2020 13:04:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	PDQ: Date of the pregnancy test does not the same day as the vaccination. Please review and correct or confirm.
Sep-30-2020 13:01:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	another query raised
Sep-30-2020 12:52:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: Date of the pregnancy test does is not the same day as the vaccination. Please review and correct or confirm.

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (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: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

Sep-28-2020 14:37:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020	Initial Entry
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4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-28-2020 14:37:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-28-2020 14:37:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-28-2020 14:37:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Define 113 <b>d Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-28-2020 14:37:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-28-2020 14:37:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (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:** 12471066

**Subject Initials:** ---

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

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

**6.a Not Done:**

Date	Location	User	Value	Reason
Sep-28-2020 14:37:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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*1. Randomization Date :*

Date	Location	User	Value	Reason
Sep-29-2020 12:27:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/29/2020	Initial Entry

*2. Randomization Number:*

Date	Location	User	Value	Reason
Sep-29-2020 12:27:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 266464	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: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-28-2020 14:37:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-28-2020 14:37:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-28-2020 16:49:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-28-2020 14:37:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-28-2020 14:37:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/28/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-28-2020 16:49:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BM9CHB</b>	Initial Entry

**5.a Sample ID**

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (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: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-28-2020 16:49:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9CHB	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-30-2020 11:34:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSDYF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 11:34:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSDYF	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-30-2020 11:34:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSDYG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 11:34:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSDYG	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-28-2020 14:38:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-28-2020 14:38:05 (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
Sep-28-2020 16:49:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-28-2020 14:38:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-28-2020 14:38:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/28/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-28-2020 16:49:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM9CH6	Initial Entry

**5.a Sample ID**

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-28-2020 16:49:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9CH6	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Sep-29-2020 12:27:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-29-2020 12:27:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-29-2020 12:27:46 (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
Sep-29-2020 23:06:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-29-2020 15:55:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-29-2020 15:39:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Date of visit is noted as 28Sep20, Yet Vaccine was given on 29Sep20. Was vaccine delayed? Please update or clarify. Thanks
Sep-29-2020 12:27:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/29/2020 08:56	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471066

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

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-29-2020 12:27:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-29-2020 12:27:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-29-2020 12:27:46 (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
Sep-29-2020 12:27:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-29-2020 12:27:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-29-2020 12:27:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-20-2020 07:55:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  <b>Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?:</b> NO	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.b*

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FAT IG UE	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HEADA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS <b>Were fever or systemic symp</b> NO <b>toms present on the last day</b> <b>the Subject Diary was compl</b> <b>eted?:</b>	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?:</b>	Initial Entry
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*2.e Symptom:*

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.f*

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?:</b>	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MUS CLE PAIN  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</b> NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSC LE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?:</b> NO	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED JOI NT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Oct-20-2020 08:21:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS <b>Were injection site reaction s present on the last day the Subject Diary was complete d?:</b> NO	Initial Entry
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**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG <b>Were injection site reaction s present on the last day th e Subject Diary was compl eted?:</b> NO	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-20-2020 07:56:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471066

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

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**1. Date:**

Date	Location	User	Value	Reason
Nov-11-2020 08:16:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-11-2020 08:16:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Applicable <b>Temperature:</b> Not Applicable <b>Temperature Unit:</b> Not Applicable <b>Temperature Location:</b> Not Applicable	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-11-2020 08:16:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-11-2020 08:16:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-11-2020 08:16:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Temperature Location:**

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1247

**Subject No:** 12471066

**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

Date	Location	User	Value	Reason
Nov-11-2020 08:16:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry



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: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable	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: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Test::</b>	Not Applicable
			<b>Result::</b>	Not Applicable
			<b>Not Done::</b>	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Nov-11-2020 08:16:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-13-2020 07:32:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry
Nov-13-2020 07:32:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-11-2020 08:17:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-13-2020 07:32:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry
Nov-13-2020 07:32:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-11-2020 08:17:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-13-2020 10:54:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Closed	Auto closed by Validation Check: VC_BEETRK001_05
Nov-13-2020 07:32:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Answered	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471066**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Nov-13-2020 07:32:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
Nov-13-2020 07:32:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-12-2020 21:53:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Reissued:Opened	DM: Sample Collected is not expected to be Not Applicable. If the sample was not collected Please mark 'Sample collected?' as 'NO' then enter the reason sample was not done in Field #4. Thank you.
Nov-12-2020 08:21:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1 : Answered	vISIT 2 NOT DONE AS PATIENT DISCONTINUED
Nov-12-2020 07:51:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1 : Opened	DMW5355203;Sample Collected is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-11-2020 08:17:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-13-2020 07:32:34 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Patient not receiving Vax 2 after po	Initial Entry

**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:** 12471066

**Subject Initials:** ---

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

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

Pretoria		(b) (4), (b) (6)	sitve swab test	
Nov-13-2020 07:32:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-11-2020 08:17:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-11-2020 08:14:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-23-2020 22:01:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-23-2020 10:32:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Prohibited Concomitant-prohibited log updated.
Oct-21-2020 19:17:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please confirm that corticosteroids were taken for BRONCHITIS (diagnosed on 15Oct20). Please also clarify if corticosteroid use would be reportable on CONCOMITANT MEDICATIONS-PROHIBITED based upon protocol section 6.5.1.
Oct-20-2020 08:20:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of First Delay:  Oct/20/2020  Reason(s) for Temporary Delay of Vaccination  RECENT SYSTEMIC CORTI COSTEROID TREATMENT	Initial Entry

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

2. Treatment Name

Date	Location	User	Value	Reason
Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-11-2020 18:09:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-11-2020 08:15:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Not applicable added as a comment
Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-11-2020 07:57:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Per eCRFs entered subject is ended with treatment phase, if correct kindly consider updating essential field on this form as Not applicable or else clarify. Thank you.
Nov-04-2020 08:56:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-02-2020 11:46:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Page has been reactivated
Oct-30-2020 12:27:43	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: As per comment

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Header Text: c4591001

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Site No: 1247

Subject No: 12471066

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: ---

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(UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	entered "use of corticosteroids", Please confirm if this needs to be recorded on the appropriate form, Thank you.
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5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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**Subject No:** 12471066

**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

Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**II. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Nov-11-2020 08:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1247

**Subject No:** 12471066

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-23-2020 13:10:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per SITE response, added to PD tracker for Clinical review
Nov-20-2020 11:04:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient did not have Vax 2 - date correct
Nov-19-2020 13:31:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: DOV at this visit is out of window (-1 day) from DOV (20/Oct/2020) at V2_VAX2_L. Please reconcile and update accordingly, else confirm date is correct as is.
Nov-16-2020 09:36:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/16/2020	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Nov-17-2020 20:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-17-2020 12:20:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient did not receive IP at V2
Nov-17-2020 10:57:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5386853;Were medications to treat fever/pain given on the last day the Subject Diary was completed? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b>  Not Applicable	Initial Entry

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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Not Applicable
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2.a Symptom:

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-17-2020 20:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-17-2020 12:20:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient did not receive IP at V2
Nov-17-2020 11:29:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5386844;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not	Initial Entry

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Visit: V3\_MONTH1\_POSTVAX2\_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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Pretoria		(b) (4), (b) (6)	Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Applicable
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2.b Symptom:

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-17-2020 20:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-17-2020 12:21:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient did not receive IP at V2
Nov-17-2020 11:34:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5386845;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.c

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

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Subject Initials: ---

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Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  Not Applicable  Not Applicable
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2.c Symptom:

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-17-2020 20:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-17-2020 12:21:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient did not receive IP at V2
Nov-17-2020 11:34:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5386846;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

2.d

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Applicable</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable</p>	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

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Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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2.d Symptom:

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-17-2020 20:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-17-2020 12:21:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient did not receive IP at V2
Nov-17-2020 11:34:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5386847;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Not Applicable
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2.e Symptom:

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-17-2020 20:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-17-2020 12:21:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient did not receive IP at V2
Nov-17-2020 11:34:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5386848;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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Pretoria		(b) (4), (b) (6)	Appl icabl e  Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?: Not Appl icabl e
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2.f Symptom:

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-17-2020 20:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Nov-17-2020 12:21:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Patient did not receive IP at V2
Nov-17-2020 11:34:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW5386849;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Not A pplica ble	Initial Entry

2.g

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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Subject Initials: ---

Generated By: (b) (4)

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Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  Not Applicable  Not Applicable
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2.g Symptom:

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-17-2020 20:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-17-2020 12:21:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient did not receive IP at V2
Nov-17-2020 11:34:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5386850;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> Not Applicable</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable</p>	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-17-2020 20:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-17-2020 12:22:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient did not receive IP at V2
Nov-17-2020 11:34:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5386851;Symptoms Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
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090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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5.a

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Appli cable  <b>Were injection site reaction</b> Not <b>s present on the last day the</b> Appli <b>Subject Diary was complet</b> cable <b>ed?:</b>	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Appli cable  <b>Were injection site reaction</b> Not <b>s present on the last day the</b> Appli <b>Subject Diary was complet</b> cable <b>ed?:</b>	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Applicable  <b>Were injection site reaction</b> Not <b>s present on the last day the</b> Appli <b>Subject Diary was complet</b> cable <b>ed?:</b>	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-17-2020 20:11:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-17-2020 12:22:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patient did not receive IP at V2
Nov-17-2020 11:09:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5386835;Reactions Occur? is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Nov-16-2020 09:37:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (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, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-16-2020 09:38:14 (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-16-2020 09:38:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-12-2021 16:42:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Feb-12-2021 07:35:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Feb-12-2021 07:32:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Feb-12-2021 07:32:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Feb-12-2021 07:32:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Changed Information

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (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, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471066**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Feb-11-2021 22:04:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	DM: Because samples were moved to Convalescent visit, Sample Collected should be 'No' and 'Sample captured in Convalescent visit' added to Item 2 per the table in CRF Completion Requirements Section 8.29.2.
Feb-11-2021 22:01:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	New query to be issued
Feb-11-2021 21:59:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Query can be addressed internally
Feb-11-2021 13:31:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 11:21:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-10-2021 23:17:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	DM: Do not issue query. Do not freeze CRF. Site to update CRF - moving data to Convalescent visit.
Nov-16-2020 19:31:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-16-2020 15:19:58 (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

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, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

				correct as appropriate.
Nov-16-2020 09:38:14 (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-16-2020 09:38:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/16/2020	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 07:35:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Convalescent visit and Visit 3 occurred on same day. Samples collected captured at convalescent visit	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-12-2021 07:32:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> Not Done	Initial Entry
Feb-11-2021 11:20:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information
Nov-16-2020 19:31:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM9FR7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-12-2021 07:32:16 (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: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1247

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

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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

Feb-11-2021 11:20:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-16-2020 19:31:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9FR7	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-12-2021 07:32:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: Not Done	Initial Entry
Feb-11-2021 11:20:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID:	Changed Information
Nov-16-2020 19:31:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRSTMD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-12-2021 07:32:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-11-2021 11:20:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-16-2020 19:31:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSTMD	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-12-2021 07:32:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: Not Done	Initial Entry
Feb-11-2021 11:21:01 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID:	Changed Information

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (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, Verified

**Site No:** 1247

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

**Subject No:** 12471066

**Subject Initials:** ---

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

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

Pretoria		(b) (4), (b) (6)		
Nov-16-2020 19:31:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSTMF	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-12-2021 07:32:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-11-2021 11:21:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-16-2020 19:31:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSTMF	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History  
Oct/16/2020**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:** 12471066**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Oct-20-2020 16:31:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-20-2020 16:25:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-20-2020 16:25:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-20-2020 16:25:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Oct/16/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-20-2020 16:25:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Oct/16/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-11-2021 17:10:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 11:53:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-11-2021 11:53:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved :  Oct/27/2020	Changed Information
Feb-11-2021 10:17:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Thanks for the response, form has been unfreeze, please update as per below query
Feb-10-2021 19:46:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	DM please unfreeze CRF for site update.
Feb-10-2021 16:18:50 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze page in order to update

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Not Complete**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471066**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Pretoria		(b) (4), (b) (6)		data
Feb-08-2021 18:18:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Oct-24-2020 10:47:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	New Information
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NO Date of Last Symptom Resolved : Oct/19/2020	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Symptoms: FEVER Symptom Present: NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NO	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Oct/16/2020 Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

4.b

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom P</b> YES <b>resent:</b>	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-21-2020 11:56:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> YES	patient confirmed new Shortness of Breath
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 11:56:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> YES	patient confirmed new Shortness of Breath
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b>	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Pretoria			Symptom NEW OR INCREASED MUSCLE PAIN Symptom NO Present:
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4.e Symptoms:

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: NO	Initial Entry

4.g

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Oct/16/2020 Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED SORE THROAT <b>Symptom</b> NO <b>Present:</b>	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NO	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Oct/16/2020 Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

4.i

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-20-2020 16:26:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
Oct/16/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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Date	Location	User	Value	Reason
Oct-21-2020 11:43:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Form Deleted	Patient did not go for local test
Oct-20-2020 16:30:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
Oct/16/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Oct-25-2020 17:58:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
Oct/16/2020

Form Version: 06-Jul-2020 21:54

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**2. Specimen Type:**

Date	Location	User	Value	Reason
Oct-20-2020 16:30:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Oct-20-2020 16:30:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Oct-20-2020 16:30:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Oct-20-2020 16:30:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> details of swab will be confirmed	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
Oct/16/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Oct-25-2020 17:58:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Oct/23/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Oct-25-2020 17:58:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Oct-25-2020 17:58:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Oct-25-2020 17:58:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Oct-25-2020 17:58:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Oct-25-2020 17:58:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> OTHER	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
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Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

7. Test Result:

Date	Location	User	Value	Reason
Oct-25-2020 17:58:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> POSITIVE	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-25-2020 18:01:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-25-2020 18:01:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Covid Illness confirmed by positive SARS_CoV_2 PCR test done at the National Health Laboratory Services in Cape Town South Africa	Changed Information
Oct-25-2020 17:58:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Oct-25-2020 17:58:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Suspected Covid Illness confirmed by positive SARS-CoV-2 nucleic acids in the specimen. PCR test done at the National Health Laboratory Services in Cape Town South Africa	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-29-2020 08:15:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
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Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC+02:00) Harare, Pretoria				
Oct-28-2020 15:20:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swered	Changed Information
Oct-28-2020 15:20:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry</b> : CLIA-certifi ed lab	Changed Information
Oct-28-2020 12:48:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Re issued:Open ed	DM1: As per CRF CR, Kindly update "CLIA-certified lab" in the specified field, Thank you.
Oct-28-2020 09:38:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: An swered	CLIA-certified lab
Oct-27-2020 13:39:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4) [REDACTED]	Query 1: Op ened	will confirm is not indicated on the FDA-cleared (including Emergency Use Authorization) diagnostic list and is not indicated as 'CLIA-certified lab' or 'ISO 15189 accredited lab' . Please verify and update as appropriate. Otherwise, please provide clarification. (b) (4) [REDACTED]

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Oct-25-2020 17:58:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry</b> : will confirm	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 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: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-20-2020 16:31:42 (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-20-2020 16:31:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-21-2020 11:46:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-20-2020 16:54:27 (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-20-2020 16:32:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Oct/16/2020	Transcription Error
Oct-20-2020 16:31:42 (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-20-2020 16:31:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 **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:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

			Oct/15/2020	
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**5.a**

Date	Location	User	Value	Reason
Oct-21-2020 11:46:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> CV23918	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-21-2020 11:46:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CV23918	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 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: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-20-2020 16:32:08 (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-20-2020 16:32:08 (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-20-2020 16:33:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-20-2020 16:32:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Oct-20-2020 16:32:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<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
Oct-20-2020 16:33:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> self swab performed	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Oct/16/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471066**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Oct-24-2020 10:48:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> YES Number of Visits or Contacts: 1	New Information
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Oct/16/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

**I.b Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

**I.b Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Oct-24-2020 10:48:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	New Information
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
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Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

**I.c Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

**I.c Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Oct-24-2020 10:49:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	New Information
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
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Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

**I.d Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> URGENT CARE	Initial Entry

**I.d Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Oct-24-2020 10:49:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	New Information
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Oct-24-2020 10:49:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i>  7	New Information
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i>  5	Initial Entry

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Oct/16/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471066**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51***I.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***I.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-24-2020 10:49:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  7	New Information
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  5	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHE R <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***I.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> OTHER	Initial Entry

***I.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Oct/16/2020

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**3. Has the subject been hospitalized due to potential COVID-19 illness?**

Date	Location	User	Value	Reason
Oct-24-2020 10:50:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Has the subject been in intensive care due to potential COVID-19 illness?  NO	New Information
Oct-20-2020 16:33:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS - Audit Trail  
Oct/16/2020

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Oct-24-2020 10:50:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History  
Oct/16/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Oct-24-2020 10:50:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HOSPITALIZATION STATUS	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Oct-24-2020 10:50:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HOSPITAL	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Mar-09-2021 15:25:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-09-2021 13:35:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirmed no other pages need update. Thank you.
Mar-08-2021 16:33:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLIQUEY: Please confirm if any further assessment CRF's should be updated? Labs, Vital Signs, etc.?
Mar-08-2021 15:11:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Site in error asked wrong page to be unfrozen, however the respiiratory treatment page (correct page) has been updated
Mar-03-2021 16:33:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Please unfreeze Oxygen CRF within this visit for site update.

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History  
Oct/16/2020**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Not Complete**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471066**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Mar-03-2021 16:26:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/23/2020	Transcription Error
Mar-03-2021 16:25:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze the Oxygen page in order for site to upload
Feb-23-2021 11:35:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) _____ _____	Query 1: Reissued:Opened	DM please unfreeze assessment CRF's in this visit for site update
Feb-22-2021 16:02:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	DM please unfreeze assessment CRF's in this visit for site update.
Feb-22-2021 12:48:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze all procedure pages in order to update data
Feb-17-2021 09:20:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) _____	Query 1: Opened	CLIQUEY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Feb-16-2021 21:51:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLIQUEY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History  
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**Form Status:** Data Complete, Not Complete

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

				obtain these information.
Oct-24-2020 10:50:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/22/2020	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Mar-03-2021 16:25:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Discharge Date: Oct/26/2020	New Information
Oct-24-2020 10:50:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Audit Trail  
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**Form Version:** 06-Jul-2020 21:53

**Form Status:**

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

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**Subject Initials:** ---

**Generated By:** (b) (4)

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Date	Location	User	Value	Reason
Mar-08-2021 15:10:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: RESPIRATORY TREATMENT - eCRF Audit Trail History  
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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: 12471066

Subject Initials: ---

Generated By: (b) (4)

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**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Mar-08-2021 15:10:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry
Mar-08-2021 15:08:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-20-2020 16:34:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Mar-08-2021 15:10:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> YES	Initial Entry
Mar-08-2021 15:08:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-20-2020 16:34:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Mar-08-2021 15:10:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HIGH FLOW OXYGEN THERA PY	Initial Entry
Mar-08-2021 15:08:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-20-2020 16:34:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: RESPIRATORY TREATMENT - eCRF Audit Trail History  
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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: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Mar-08-2021 15:10:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HIGH FLOW OXYGEN THERA PY	Initial Entry
Mar-08-2021 15:08:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-20-2020 16:34:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Mar-08-2021 15:10:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/23/2020	Initial Entry
Mar-08-2021 15:08:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-20-2020 16:34:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Mar-08-2021 15:10:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  Oct/24/2020	Initial Entry
Mar-08-2021 15:08:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-20-2020 16:34:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - eCRF Audit Trail History  
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Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-20-2020 16:36:25 (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
Feb-12-2021 18:22:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Feb-12-2021 07:42:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Feb-12-2021 07:42:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  COVID-19  Date of Diagnosis:  Oct/23/2020	Changed Information
Feb-11-2021 17:12:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	CLIQUEY: COVID-19 Date of Diagnosis is 15Oct2020 however Local positive COVID-19 test date was 23Oct2020. Date of Diagnosis should match positive test date in Local or Central. Please update or clarify.
Feb-11-2021 11:54:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	SOD page updated

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - eCRF Audit Trail History  
Oct/16/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Feb-11-2021 10:18:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 4: Reissued:Opened	Thanks for the response, form has been unfreeze, please update as per below query
Feb-10-2021 19:46:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Candidate	DM please unfreeze CRF for site update.
Feb-10-2021 15:46:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Please unfreeze page in order to update data
Feb-08-2021 18:19:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	CLIQUEY: COVID-19 Date of Diagnosis is 15Oct2020 however Local positive COVID-19 test date was 23Oct2020. Date of Diagnosis should match positive test date in Local or Central. Please update or clarify.
Nov-13-2020 20:09:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Closed	Response satisfies query
Nov-13-2020 18:04:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Updated
Nov-13-2020 10:02:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Reissued:Opened	Please add conmed as per section 8.49 of the eCRF as per eCRF guidelines section 8.49
Nov-12-2020 09:45:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 3: Closed	Response satisfies query
Nov-12-2020 08:24:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
Oct/16/2020**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Not Complete**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471066**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Nov-12-2020 08:24:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  COVID-19  Date of Diagnosis:  Oct/15/2020	New Information
Nov-12-2020 07:52:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 3: Opened	CLIQUEY: Given that the subject has a local positive COVID-19 test result, please clarify the diagnosis and review to determine whether the diagnosis should include COVID-19? please update as appropriate.
Nov-06-2020 13:33:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	According to Protocol Section 6.5.1. - "Receipt of systemic corticosteroids (20 mg or more per day of prednisone or equivalent) for 14 days or longer is prohibited from 28 days prior to enrollment to Visit 3". Should logline be reactivated?
Nov-04-2020 17:13:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	Please consider adding prohibited medication into eCRF as per eCRF guidelines section 8.49
Oct-23-2020 22:00:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - eCRF Audit Trail History  
Oct/16/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Not Complete

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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Oct-23-2020 10:31:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirmed event bronchitis.
Oct-21-2020 19:13:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please add event of 'bronchitis' and all relevant details to the AE CRF. Thank you.
Oct-20-2020 16:36:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Bronchitis  Date of Diagnosis:  Oct/15/2020	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-20-2020 16:36:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> 3	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History  
Oct/16/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-24-2020 10:51:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-24-2020 10:48:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-20-2020 16:36:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Oct-24-2020 10:51:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-24-2020 10:48:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-20-2020 16:36:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Oct-24-2020 10:51:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-24-2020 10:48:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-20-2020 16:36:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History  
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**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-24-2020 10:51:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-24-2020 10:48:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-20-2020 16:36:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

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Subject Initials: ---

Generated By: (b) (4)

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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			Lab Normal Range: Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare,	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Sponsor-Defined Ide Not Applic	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 **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:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Pretoria			<b>ntifier:</b>	able	
			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 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

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	
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5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Site No: 1247

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Subject Initials: ---

Generated By: (b) (4)

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

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Site No: 1247

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.f

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 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: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Oct/16/2020 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Lab Normal Range: Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Sponsor-Defined Ide Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Pretoria			<b>ntifier:</b>	able	
			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

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Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d

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**Header Text:** c4591001

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**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

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Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

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Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	
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5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Subject Initials:** ---

**Generated By:** (b) (4)

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Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
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Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Not Done:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f LNMT**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
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Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	
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5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)



**Header Text:** c4591001

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**Site No:** 1247

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

**5.h Sponsor ID:**

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Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Result:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Not Done:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h LNMT**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Oct/16/2020 Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	
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5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Oct-20-2020 16:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History  
Oct/16/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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*1. Date:*

Date	Location	User	Value	Reason
Oct-20-2020 16:38:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Oct-20-2020 16:38:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Applicable <b>Systolic::</b> Not Applicable <b>Diastolic::</b> Not Applicable <b>Respiratory Rate in re</b> Not Applicable <b>spirations/minute:</b> licable <b>Heart Rate in beats/mi</b> Not Applicable <b>nutte:</b> licable	Initial Entry

*2.a Record Identifier:*

Date	Location	User	Value	Reason
Oct-20-2020 16:38:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

*2.a Systolic:*

Date	Location	User	Value	Reason
Oct-20-2020 16:38:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

*2.a Diastolic:*

Date	Location	User	Value	Reason
Oct-20-2020 16:38:06 (UTC+02:00) Harare,	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
Oct/16/2020

**Form Version:** 15-Sep-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Pretoria				
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**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Oct-20-2020 16:38:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Oct-20-2020 16:38:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**I. Date:**

Date	Location	User	Value	Reason
Oct-20-2020 16:38:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-20-2020 16:38:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> <b>Record Identifier:</b> Not Applicable : le <b>Oxygen Saturation:</b> Not Applicable le	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-20-2020 16:38:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Oct-20-2020 16:38:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: OXYGENATION PARAMETERS - eCRF Audit Trail History  
Oct/16/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Oct-20-2020 16:38:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Oct-20-2020 16:38:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Oct-20-2020 16:38:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-20-2020 16:39:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-20-2020 16:39:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-20-2020 16:39:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<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
Oct-20-2020 16:39:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Oct-20-2020 16:39:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
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090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/16/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1247

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Oct-20-2020 16:39:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: IMAGING - eCRF Audit Trail History  
Oct/16/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-20-2020 16:39:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Oct-20-2020 16:39:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Oct-20-2020 16:39:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Oct-20-2020 16:39:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/16/2020

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1247

**Subject No:** 12471066

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail  
History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-06-2021 09:53:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/16/2020	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Feb-06-2021 09:53:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/16/2020

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: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-06-2021 09:53:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-06-2021 09:53:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-11-2021 22:00:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 11:50:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Feb-10-2021 23:19:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM RQ1: Please refer to CRF Completion Requirements Section 8.24.4 and update the SAMP TRK CRF at V3 and Convalescent visit accordingly. When both visits occur same day, serum samples are recorded at convalescent visit.
Feb-10-2021 14:36:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Barcodes not entered as this visit and V3 occurred on the same day

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/16/2020

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: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Feb-08-2021 11:51:34 (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.
Feb-06-2021 09:53:20 (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.
Feb-06-2021 09:53:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-11-2021 11:50:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BM9FR7</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 11:50:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM9FR7	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-11-2021 11:51:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BRSTMD</b>	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/16/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1247

**Subject No:** 12471066

**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

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-11-2021 11:51:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSTMD	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-11-2021 11:51:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRSTMF	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-11-2021 11:51:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRSTMF	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1247

**Subject No:** 12471066

**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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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Date	Location	User	Value	Reason
Nov-05-2020 12:01:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Deleted	Transcription Error
Oct-21-2020 21:53:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**I. Category:**

Date	Location	User	Value	Reason
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-25-2020 18:03:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	New Information
Oct-21-2020 21:53:37 (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-15-2020 16:25:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	AE was removed per query
Nov-13-2020 13:26:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Response does not satisfy query
Nov-05-2020 12:01:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-04-2020 17:12:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please consider deleting entry as per section 4.11 of the eCRF guidelines
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-25-2020 18:03:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	New Information
Oct-21-2020 21:53:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Oct-26-2020 16:18:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	moved to COVID ILL
Oct-25-2020 18:03:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<u>Data Entry:</u>	New Information
Oct-24-2020 10:21:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-24-2020 10:21:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<u>Data Entry:</u> Bronchitis, under investigation	New Information
Oct-23-2020 19:43:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Reissued:Opened	GPD Clin: Thank you for confirming the cause of bronchitis is viral infection. Can you please update AE Log accordingly. Thanks
Oct-23-2020 08:27:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Viral infection.
Oct-22-2020 20:53:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Can you please confirm, if pathogen causing Bronchitis is known? Please review and update AE term as needed. Thanks
Oct-21-2020 21:53:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Bronchitis	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Oct-25-2020 18:04:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<u>Data Entry:</u>	New Information
Oct-21-2020 21:53:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/15/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Oct-25-2020 18:04:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<u>Data Entry:</u>	New Information
Oct-21-2020 21:53:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Oct-25-2020 18:06:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<u>Data Entry:</u>	New Information
Oct-21-2020 21:53:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

7. Is the adverse event serious?

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Header Text: c4591001

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Generated By: (b) (4)

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If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-26-2020 12:35:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	event deleted
Oct-25-2020 18:05:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Oct-25-2020 18:05:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-25-2020 18:05:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b>	New Information
Oct-25-2020 15:47:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: Bronchitis, under investigation(Onset date:15Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-25-2020 15:47:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Oct-24-2020 10:43:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> YES Did this serious event require o	Not SAE as this is a potential COVID illness

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

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			r prolong hospitalization? NO	
Oct-24-2020 10:21:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Bronchitis, under investigation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-24-2020 10:20:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Oct-24-2020 10:20:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Bronchitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-24-2020 10:20:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> YES Did this serious event require o r prolong hospitalization?  YES	New Information
Oct-21-2020 21:53:37 (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
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Header Text: c4591001

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Subject No: 12471066

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

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Oct-25-2020 18:05:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<u>Data Entry:</u>	New Information
Oct-21-2020 21:53:37 (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
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Oct-25-2020 18:06:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<u>Data Entry:</u>	New Information
Oct-24-2020 10:23:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment (s), this event is due to:  OTHER  <i>If Other, specify:</i>  under investigation	New Information
Oct-22-2020 10:38:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment (s), this event is due to:  OTHER  <i>If Other, specify:</i>  Viral	Transcription Error
Oct-21-2020 21:53:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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**Subject No:** 12471066

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Deleted, Locked, Frozen, Verified

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-25-2020 18:06:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<u>Data Entry:</u>	New Information
Oct-21-2020 21:53:37 (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
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Oct-25-2020 18:06:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<u>Data Entry:</u>	New Information
Oct-21-2020 21:53:37 (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
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Oct-25-2020 18:07:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<u>Data Entry:</u>	New Information
Oct-21-2020 21:53:37 (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
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Header Text: c4591001

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Form Status: Data Complete, Deleted, Locked, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

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Generated By: (b) (4)

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Oct-30-2020 14:52:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Form updated as not applicable
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-28-2020 19:48:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	New information pending AE investigation
Oct-27-2020 17:21:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	DM: Please update Item #13 when data is available.
Oct-26-2020 14:21:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	AE still under investigation by PI
Oct-26-2020 13:45:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM: Please update AE end date in InForm by responding to question, 'Is the adverse event still ongoing?'. Thanks
Oct-25-2020 18:07:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b>	New Information
Oct-25-2020 18:03:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Answer Auto Query
Oct-24-2020 13:01:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 3: Reissued:Opened	Thanks for confirming end date. Kindly update end data at adverse event still ongoing? Thank you.
Oct-24-2020 10:24:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Oct-24-2020 10:24:24 (UTC+02:00) Harare,	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b> NOT RECOVERED/NOT RESO	New Information

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

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Subject No: 12471066

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Pretoria			LVED	
Oct-24-2020 10:21:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE Bronchitis, under investigation: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-23-2020 08:29:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	End date is 19 Oct 2020.
Oct-23-2020 08:27:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Bronchitis: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-23-2020 08:27:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry
Oct-23-2020 08:23:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-23-2020 08:23:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Oct-23-2020 08:22:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Bronchitis: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-23-2020 08:22:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-23-2020 08:22:49 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Deleted, Locked, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Pretoria		(b) (4), (b) (6)		
Oct-22-2020 13:34:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Data does not match source
Oct-21-2020 21:53:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESO LVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-25-2020 18:07:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<b>Data Entry:</b>	New Information
Oct-21-2020 21:53:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Oct-29-2020 09:22:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Oct-23-2020 08:29:14 (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
Oct-23-2020 08:29:14 (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
Oct-23-2020 08:29:14 (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
Oct-23-2020 08:29:14 (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
Oct-23-2020 08:29:14 (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
Oct-23-2020 08:29:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

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Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

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7. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-23-2020 08:29:14 (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
Oct-23-2020 08:29:14 (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
Oct-23-2020 08:29:14 (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
Oct-23-2020 08:29:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-23-2020 08:29:30 (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
Oct-23-2020 08:29:30 (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
Oct-23-2020 08:29:30 (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
Oct-23-2020 08:29:30 (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
Oct-23-2020 08:29:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Status:

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Nov-16-2020 18:04:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Not needed as prednisone use was only 4 days
Nov-13-2020 18:03:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Logline reactivated as per monitor instruction
Nov-03-2020 13:24:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Nov-02-2020 11:45:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Oct-26-2020 15:39:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Query response: deleted due to not needed on this page
Oct-23-2020 08:57:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Locked, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-16-2020 18:00:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Oct-23-2020 08:57:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry
Oct-23-2020 08:54:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-23-2020 08:30:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-16-2020 18:00:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-23-2020 08:57:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CORTICOSTEROIDS	Initial Entry
Oct-23-2020 08:54:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-23-2020 08:30:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-16-2020 18:00:52 (UTC+02:00) Harare,	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information

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Pretoria				
Oct-23-2020 08:57:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry
Oct-23-2020 08:54:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-23-2020 08:30:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

#### 4. Medication:

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Nov-16-2020 18:15:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 3: Closed	Response satisfies query
Nov-16-2020 18:00:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Nov-16-2020 18:00:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-16-2020 15:24:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Reissued:Opened	Page unfrozen
Nov-16-2020 13:10:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Please unlock page in order to delete data
Nov-14-2020 22:46:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 3: Reissued:Opened	please delete all the information. this con med is NOT prohibited if given for 4 days. Thanks
Nov-14-2020 21:32:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Logline inactivated
Nov-14-2020 16:05:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 3: Opened	Clin: Please note this medication does not meet the dose/duration criteria listed in section 6.5.1. Please delete all data from this

				CRF. Thanks
Nov-03-2020 20:17:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Closed	response satisfies query
Nov-03-2020 13:24:22 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Answered	Changed data per query
Nov-02-2020 20:05:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	CLINQUERY: As per protocol section 6.5.1 prohibited corticosteroids >= 20 mg /day for >= 14 days are prohibited, as reported subject only received for 5 days. Therefore corticosteroids at this dose do not need to be captured on this page. Please update.
Oct-27-2020 14:48:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Oct-26-2020 16:19:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Candidate	response satisfies query
Oct-26-2020 15:39:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Query response: deleted due to not needed on this page
Oct-26-2020 14:36:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CLINQUERY: As per protocol section 6.5.1 prohibited corticosteroids >= 20 mg /day for >= 14 days are prohibited, as reported subject only received for 5 days. Therefore corticosteroids at this dose do not need to be captured on this page. Please update.
Oct-23-2020 08:57:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Prednisone	Initial Entry
Oct-23-2020 08:54:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Initial Entry

Oct-23-2020 08:30:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
<b>5. Dose:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-16-2020 18:01:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-23-2020 08:57:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 20	Initial Entry
Oct-23-2020 08:54:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-23-2020 08:30:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
<b>6. Dose Unit:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-16-2020 18:01:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-23-2020 08:57:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mg	Initial Entry
Oct-23-2020 08:54:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-23-2020 08:30:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
<b>7. Dose Frequency:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-16-2020 18:01:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-23-2020 08:57:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> QD	Initial Entry
Oct-23-2020 08:54:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

Oct-23-2020 08:30:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**8. Route:**

Date	Location	User	Value	Reason
Nov-16-2020 18:03:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-23-2020 08:57:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL	Initial Entry
Oct-23-2020 08:54:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Oct-23-2020 08:30:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Start Date:**

Date	Location	User	Value	Reason
Nov-16-2020 18:15:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Closed	Response satisfies query
Nov-16-2020 18:03:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-16-2020 18:03:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-16-2020 15:42:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Page is unfrozen.

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Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Locked, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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9. Start Date:

Date	Location	User	Value	Reason
Nov-16-2020 13:57:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Candidate	DM: Please unfreeze so site can delete data as per query text above. thanks
Oct-23-2020 08:57:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/15/2020	Initial Entry
Oct-23-2020 08:54:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Oct-23-2020 08:30:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Nov-16-2020 18:03:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Oct-23-2020 08:57:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: Oct/19/2020	Initial Entry
Oct-23-2020 08:54:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Oct-23-2020 08:30:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

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Site No: 1247

Subject No: 12471066

Generated By: (b) (4)

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Oct-23-2020 08:31:20 (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
Oct-23-2020 08:31:20 (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
Oct-23-2020 08:31:20 (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
Oct-23-2020 08:31:20 (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
Oct-23-2020 08:31:20 (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
Oct-23-2020 08:31:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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**Site No:** 1247

**Subject No:** 12471066

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

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**1. Transfusion Type:**

Date	Location	User	Value	Reason
Oct-23-2020 08:32:06 (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
Oct-23-2020 08:32:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry



Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471066

Subject Initials: ---

Generated By: (b) (4)

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**I. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Dec-18-2020 20:41:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-18-2020 07:21:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-18-2020 07:21:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/15/2020	Transcription Error
Dec-17-2020 18:00:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPD CLIN: Please note that per the SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 CRF the date the first COVID symptom started was 15/Oct/2020 however the date of discontinuation is noted as 16/Oct /2020. Please clarify or reconcile the date on both CRFs. Thanks
Dec-17-2020 14:35:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-17-2020 14:35:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/16/2020	Changed Information
Dec-11-2020 17:41:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLIN: Please update the date of discontinuation to the date the first COVID symptom started. Thank you.

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

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Subject Initials: ---

Generated By: (b) (4)

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Nov-10-2020 12:25:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/10/2020	Initial Entry
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2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-10-2020 12:25:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-10-2020 17:23:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-10-2020 12:25:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-10-2020 12:24:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is NO LONGER MEETS ELIGIBILITY CRITERIA but "Specify Status" is missing.
Nov-10-2020 12:24:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Nov-10-2020 12:24:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO LONGER MEETS ELIGIBILITY CRITERIA	New Information
Nov-09-2020 22:26:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	GPD CLIN: Per the COV ILL CRFs the subject tested positive for COVID and was symptomatic thus please complete the EOT CRF to note she has been discontinued from treatment since she is no longer eligible per

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**Header Text:** c4591001

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**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**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:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

				exclusion criterion #5. Thank you.
Nov-06-2020 18:05:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 08:16:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Noted
Nov-02-2020 20:31:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLIN: Per the COV ILL CRFs the subject tested positive for COVID and was symptomatic thus please complete the EOT CRF to note she has been discontinued from treatment since she is no longer eligible per exclusion criterion #5. Thank you.

**4. Specify Status:**

Date	Location	User	Value	Reason
Nov-10-2020 12:25:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Patient tested positive for COVID 19 and was symptomatic prior to visit 2	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (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:** 12471066

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-22-2021 15:32:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/5/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1247

**Subject No:** 12471066

**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

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Feb-22-2021 15:34:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 15:33:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-22-2021 15:33:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1247

**Subject No:** 12471066

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-22-2021 15:34:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/8/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-22-2021 15:34:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADD ITIONAL VACCINATION	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1247

**Subject No:** 12471066

**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

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*1. Withdrawal of Consent Date :*

Date	Location	User	Value	Reason
Feb-22-2021 15:34:36 (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:** 12471066

**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

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*1. Date of Collection / Notification of Death:*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-22-2021 15:34:59 (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:** 12471066

**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

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-10-2020 12:24:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	New Information
Sep-29-2020 12:27:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-28-2020 14:34:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Dec-18-2020 07:21:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/15/2020	Transcription Error
Dec-17-2020 14:35:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/16/2020	Changed Information
Nov-10-2020 12:25:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/10/2020	Initial Entry
Nov-10-2020 12:24:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/29/2020	New Information
Sep-29-2020 12:27:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/29/2020	Initial Entry
Sep-28-2020 14:34:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/28/2020	Initial Entry

090177e196ae2fc1\Final\Final On: 01-Apr-2021 03:50 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1247

**Subject No:** 12471066

**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

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-11-2020 11:20:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry