

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1247

Subject No: 12471135

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: 12471135

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/30/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12471135]
2.	Birth Date:	UNK/UNK/1951
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1247

Subject No: 12471135

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: 12471135

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

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:	[Asthma]
	Start Date:	UNK/UNK/1991
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Post Menopausal]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/30/2020
2.	Weight:	[43.0]
3.	Unit:	kg
4.	Height:	[161.9]
5.	Unit:	cm
6.	Body Mass Index:	[16.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.4]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

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

Lab Result

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

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/30/2020
2.	Randomization Number:	[266614]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM9CMM]
5.b	Sample ID	[BRSF2X]
5.c	Sample ID	[BRSF2Y]

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM9CMY]
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090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/30/2020 13:39
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

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1247

Subject No: 12471135

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
----	--	---

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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 Done _____	Comments
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	Comments

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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?	Not Done _____	Comments
3.	Injection Site Location:	Not Done _____	Comments
4.	Injection Site Body Side:	Not Done _____	Comments
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	Comments
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	Comments
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	Comments

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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

Vital Signs

1.	Date:	Not Done _____ //	Comments
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Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	Temperature:	Not Done _____ []	Comments
	Unit:	Not Done _____ _____	Comments
	Temperature Location:	Not Done _____ _____	Comments

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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

Lab Urinalysis

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

Lab Result

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

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ []
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090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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

Vaccination

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

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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: 12471135

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	Nov/23/2020
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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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	Comments
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	Comments
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	Comments

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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?	Not Applicable	Comments
3.	Injection Site Location:	Not Applicable	Comments
4.	Injection Site Body Side:	Not Applicable	Comments
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	Comments
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	Comments
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	Comments

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/23/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM9FTL]
5.b	Sample ID	[BRY9KF]
5.c	Sample ID	[BRY9KG]

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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: 12471135

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: POT_COVID_ILL - New Unscheduled Visit **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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1247

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

Subject No: 12471135

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: 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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1247

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

Subject No: 12471135

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 1 - Unscheduled Visit on
Feb/18/2021

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: 12471135

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/18/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Feb/18/2021

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/18/2021

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/18/2021 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[Patient reported local injection site pain, No Covid illness suspected]

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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Left Middle Cerebral Artery Infarct	Oct/21/2020 UNK: UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	Chronic cerebellar infarcts	Oct/23/2020 11:34	YES	Repeating Pages
3.	ADVERSE EVENT	3	Cerebral atrophy	Oct/23/2020 11:34	YES	Repeating Pages
4.	ADVERSE EVENT	4	Local injection site pain	Feb/17/2021 UNK: UNK	YES	Repeating Pages

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left Middle Cerebral Artery Infarct]
4.	Start Date Time:	Oct/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? YES Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Pt.68 years old; and 50 pack year history of smoking as risk factors for event.]
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020413905]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chronic cerebellar infarcts]
4.	Start Date Time:	Oct/23/2020 11:34
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [CT finding]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Cerebral atrophy]
4.	Start Date Time:	Oct/23/2020 11:34
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [CT Findings]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

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Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Local injection site pain]
4.	Start Date Time:	Feb/17/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1247

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

Subject No: 12471135

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	Repeating Pages

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

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

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1247

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

Subject No: 12471135

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	Repeating Pages

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

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

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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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Concomitant Medications

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

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1247

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

Subject No: 12471135

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	Repeating Pages

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

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

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1247

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

Subject No: 12471135

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	Repeating Pages

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

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 _____	Comments
2.	Date of Transfusion:	Not Applicable _____ //	Comments

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/21/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1247

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

Subject No: 12471135

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: 12471135

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: 12471135

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: 12471135

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?	

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1247

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

Subject No: 12471135

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: 12471135

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: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1247

Subject No: 12471135

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: 12471135

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/1/2021
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, Verified

Site No: 1247

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

Subject No: 12471135

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: 12471135

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/2/2021
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: 12471135

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

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 _____ //	Comments
----	---	-------------------------------	--------------------------

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/16/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/16/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Feb/16/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/16/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRKR5Y]
5.b	Sample ID	[BRYB2J]
5.c	Sample ID	[BRYB2K]

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/16/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRKR5R]
-----	-----------	----------

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/16/2021 10:33
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: DATE OF VISIT

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](#)

Date of Visit

1.	Date of Visit	Mar/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/9/2021 09:31
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

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: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Treatment

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: 12471135

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/21/2020

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: 12471135

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: 12471135

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: 12471135

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-01-2020 06:59:10 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

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

[Back to Form](#)

Item	Date	User	Comment
2	Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

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

[Back to Form](#)

Item	Date	User	Comment
3	Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

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

[Back to Form](#)

Item	Date	User	Comment
4	Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

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	Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

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	Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

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	Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

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	Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Nov-23-2020 11:06:04 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient discontinued treatment post SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
1	Nov-23-2020 11:06:04 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment post SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
2	Nov-23-2020 11:06:04 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment post SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.c	Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.d	Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.f	Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.g	Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.h	Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.a	Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - Comments

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.c	Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Nov-23-2020 11:07:17 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient discontinued treatment after SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
1	Nov-23-2020 11:07:17 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient discontinued treatment after SAE ----- Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
2.a	Nov-23-2020 11:07:17 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient discontinued treatment after SAE ----- Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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Item	Date	User	Comment
2.a	Nov-23-2020 11:07:17 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient discontinued treatment after SAE ----- Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
2.a	Nov-23-2020 11:07:17 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient discontinued treatment after SAE ----- Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient discontinued treatment after SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
1	Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
2	Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient discontinued treatment after SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

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Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

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

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Item	Date	User	Comment
3	Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
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Header Text: c4591001

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Item	Date	User	Comment
4	Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

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Form Version: 15-Sep-2020 21:51

Site No: 1247

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Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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

Subject Initials: ---

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

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Item	Date	User	Comment
5	Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient discontinued treatment after SAE ----- Not Done

Header Text: c4591001

Visit: V2_VAX2_L

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Site No: 1247

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Item	Date	User	Comment
6.a	Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient discontinued treatment after SAE ----- Not Done

Header Text: c4591001

Visit: V2_VAX2_L

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Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient discontinued treatment after SAE ----- Not Done

Header Text: c4591001

Visit: V2_VAX2_L

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Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
6.a	Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient discontinued treatment after SAE ----- Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Nov-23-2020 11:07:57 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient discontinued treatment after SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
1	Nov-23-2020 11:07:57 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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Item	Date	User	Comment
2	Nov-23-2020 11:07:57 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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

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Item	Date	User	Comment
3	Nov-23-2020 11:07:57 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
4	Nov-23-2020 11:07:57 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient discontinued treatment after SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient discontinued treatment after SAE <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Patient discontinued treatment after SAE Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
2	Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
3	Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

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-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
5	Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Patient discontinued treatment after SAE ----- Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
6	Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
7	Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
8	Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - Comments

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

Subject Initials: ---

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

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Item	Date	User	Comment
9	Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
10	Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
11	Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient discontinued treatment after SAE
			Not Done

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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.b	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.c	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.d	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.e	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.f	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.g	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.h	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.a	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Patient did not have vaccination Visit 2 due to discontinuation post SAE
			Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: MEDICATION ERROR - 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	Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: MEDICATION ERROR - 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	Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: MEDICATION ERROR - 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	Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: MEDICATION ERROR - 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	Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: MEDICATION ERROR - 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	Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: MEDICATION ERROR - 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	Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: MEDICATION ERROR - 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	Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: MEDICATION ERROR - 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	Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: MEDICATION ERROR - 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	Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: MEDICATION ERROR - 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	Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: MEDICATION ERROR - 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	Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
- Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Oct-22-2020 13:11:57 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
- Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Oct-22-2020 13:11:57 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
- Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Oct-22-2020 13:11:57 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
- Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Oct-22-2020 13:11:57 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
- Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Oct-22-2020 13:11:57 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
- Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Oct-22-2020 13:11:57 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
1	Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Item	Date	User	Comment
2	Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

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

Subject Initials: ---

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

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Item	Date	User	Comment
3	Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Item	Date	User	Comment
4	Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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Item	Date	User	Comment
5	Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
6	Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
7	Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
8	Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
9	Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
10	Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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	Oct-22-2020 13:14:31 (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: 12471135

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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	Oct-22-2020 13:14:31 (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: 12471135

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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	Oct-22-2020 13:14:31 (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: 12471135

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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	Oct-22-2020 13:14:31 (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: 12471135

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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	Oct-22-2020 13:14:31 (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: 12471135

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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	Oct-22-2020 13:14:31 (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: 12471135

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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	Oct-22-2020 13:14:31 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: TRANSFUSIONS - 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	Oct-22-2020 13:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: TRANSFUSIONS - 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	Oct-22-2020 13:14:56 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: TRANSFUSIONS - 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	Oct-22-2020 13:14:56 (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: 12471135

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
Form	Feb-22-2021 11:23:34 (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: 12471135

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 11:23:34 (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: 12471135

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 11:23:58 (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: 12471135

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 11:23:58 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Feb-16-2021 12:29:50 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Feb-16-2021 12:32:55 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	COMMENT ENTERED IN ERROR
Form	Feb-16-2021 12:31:28 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	NOT APPLICABLE

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Item	Date	User	Comment
3	Feb-16-2021 12:32:06 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - 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
3	Mar-09-2021 09:11:54 (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: 12471135

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-16-2021 09:51:48 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated

Affidavit:

N/A

Haylene Nell	Approved	Jan-27-2021 14:57:26 (UTC+02:00) Harare, Pretoria	BOOK	Signed
--------------	----------	---	------	--------

Affidavit:

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

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

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

(b) (6)	N/A	Nov-23-2020 11:03:56 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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Affidavit:

N/A

Haylene Nell	Approved	Nov-12-2020 15:34:14 (UTC+02:00) Harare, Pretoria	BOOK	Signed
--------------	----------	---	------	--------

Affidavit:

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

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

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

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-30-2020 13:30:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 13:30:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-30-2020 13:31:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/30/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-30-2020 13:30:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12471135	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-30-2020 13:30:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: UNK/UNK/1951	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-30-2020 13:31:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-30-2020 13:31:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 13:31:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

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-01-2020 06:58:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1247

Subject No: 12471135

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
Oct-01-2020 06:59:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-01-2020 06:59:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-01-2020 06:59:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

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
Oct-02-2020 07:29:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Ter m: Start Date: UNK/UNK/19 91 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-02-2020 07:29:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 08:17:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	Response satisfies query
Oct-05-2020 07:13:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The participant is not currently receiving/plans to receive systemic corticosteroids with the exception of Inhaled Steroids due to this condition.
Oct-02-2020 20:37:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: The subject presents at screening with ongoing asthma. Please confirm that participant is or is not currently receiving/plans to receive systemic corticosteroids with the exception of

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

				Inhaled Steroids due to this condition.
Oct-02-2020 07:29:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Asthma	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Oct-02-2020 07:29:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1991	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Oct-02-2020 07:29:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-02-2020 07:29:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Post Menopausal Start Date: UNK/UNK/2002 Ongoing: YES	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

I.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-02-2020 07:29:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 07:29:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Post Menopausal	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Oct-02-2020 07:29:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2002	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Oct-02-2020 07:29:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1247

Subject No: 12471135

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
Oct-01-2020 07:00:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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: 12471135

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 43.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 161.9	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16.4	Initial Entry

7.a

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - 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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-01-2020 07:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.4 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable
			Result::	Not Applicable
			Not Done::	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-01-2020 07:01:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

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
Oct-01-2020 07:02:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-01-2020 07:02:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 266614	Initial Entry

Header Text: c4591001
 Visit: V1_DAY1_VAX1_L
 Form Version: 22-Apr-2020 21:03
 Site No: 1247
 Subject No: 12471135
 Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
 eCRF Audit Trail History
 Form Status: Data Complete, Locked, Frozen, Verified
 Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital
 Subject Initials: ---
 Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Oct-01-2020 07:02:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-01-2020 07:02:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-01-2020 10:51:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 07:02:14 (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.
Oct-01-2020 07:02:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-01-2020 10:51:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9CMM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Oct-01-2020 10:51:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM9CMM	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-01-2020 10:51:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSF2X	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 10:51:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSF2X	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-01-2020 10:52:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSF2Y	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 10:52:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSF2Y	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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-01-2020 07:02:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-01-2020 07:02:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-01-2020 10:51:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 07:02:23 (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-01-2020 07:02:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-01-2020 10:51:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9CMY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Oct-01-2020 10:51:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM9CMY	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-01-2020 07:02:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-01-2020 07:02:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-01-2020 07:02:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-01-2020 07:02:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 13:39	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-01-2020 07:02:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-01-2020 07:02:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

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

Date	Location	User	Value	Reason
Oct-01-2020 07:02:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-01-2020 07:02:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Oct-01-2020 07:02:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1247

Subject No: 12471135

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
Oct-01-2020 07:03:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DIA RY COLLECTED FOR THIS SUBJ ECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-23-2020 11:06:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Nov-23-2020 11:06:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Done Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Done	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Done	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	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-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Done	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	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-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

2.d

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Do ne Were fever or systemic sympt Not oms present on the last day th Do e Subject Diary was complete ne d?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Do ne Were fever or systemic sympt Not oms present on the last day th Do e Subject Diary was complete ne d?:	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Done Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Done	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Not Do ne Not Do ne
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2.g Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	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-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2.h

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	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-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: Not Done Were injection site reactions present on the last day the Subject Diary was completed?: Not Done	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Pretoria		(b) (4), (b) (6)		
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: Not Done Were injection site reactions present on the last day the Subject Diary was completed?: Not Done	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: Not Done Were injection site reactions present on the last day the Subject Diary was completed?: Not Done	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-23-2020 11:06:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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I. Date:

Date	Location	User	Value	Reason
Nov-23-2020 11:07:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-23-2020 11:07:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Temperature: Not Done Temperature Unit: Not Done Temperature Location:: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-23-2020 11:07:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-23-2020 11:07:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-23-2020 11:07:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-23-2020 11:07:17 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - 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

Pretoria	(b) (4), (b) (6)
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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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Done
			Result::	Not Done
			Not Done::	Not Done

6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Nov-23-2020 11:07:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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-23-2020 11:07:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-23-2020 11:07:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-23-2020 11:07:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 11:07:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Route:

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Nov-23-2020 11:08:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-23-2020 11:03:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/23/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Appli cable Were fever or systemic symp Not toms present on the last day Appli the Subject Diary was compl cable eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (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-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Appli cable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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.b Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (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-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

2.d

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicable Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicable Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (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-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Appli cable Were fever or systemic symp Not toms present on the last day Appli the Subject Diary was compl cable eted?:	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	Symptom:: Not Applicable Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	
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2.g Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.h

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable Symptom:: Not Applicable Were fever or systemic symptoms present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: Not Appli cable Were injection site reactions Not present on the last day the S Appli ubject Diary was completed cable ?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	Not Applicable	
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: Not Applicable Were injection site reactions present on the last day the Subject Diary was completed?: Not Applicable	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: Not Applicable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (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, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

			Were injection site reactions present on the last day the subject Diary was completed?:	Not Applicable
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-23-2020 11:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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-23-2020 11:05:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-23-2020 11:05:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-24-2020 07:31:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-23-2020 13:33:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-23-2020 11:05:36 (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-23-2020 11:05:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Nov-24-2020 07:31:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9FTL	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 07:31:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM9FTL	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-24-2020 07:32:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRY9KF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 07:32:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRY9KF	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-24-2020 07:32:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRY9KG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 07:32:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRY9KG	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/18/2021

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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-18-2021 11:14:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/18/2021	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/18/2021

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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I. Assessments

Date	Location	User	Value	Reason
Feb-18-2021 11:18:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-18-2021 11:15:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Feb-18-2021 11:15:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/18/2021

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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1. Contact Type:

Date	Location	User	Value	Reason
Feb-18-2021 11:17:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-18-2021 11:18:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 11:18:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Feb/18/2021 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION	Transcription Error
Feb-18-2021 11:17:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Contact" is missing.
Feb-18-2021 11:17:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Contact Outcome: VISIT NOT ARRANGED, REACTION NO LONGER PRESENT	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Feb-18-2021 11:20:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Patient reported local injection site pain, No Covid illness suspected	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

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Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

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Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

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Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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1. Category:

Date	Location	User	Value	Reason
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-10-2020 10:04:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 4: Clo sed	Discrepancy has been closed.
Nov-10-2020 09:27:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Clo sed	Response satisfies query
Nov-10-2020 07:43:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Ans wered	Left Middle Cerebral infarct is the event reported as SAE. Chronic cerebral infarcts and cerebral atrophy are pre-existing conditions diagnosed at the time of the event by CT scan. These will be reported as AEs, as they not part of the SAE term
Nov-10-2020 07:43:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Ans wered	Left Middle Cerebral infarct is the event reported as SAE. Chronic cerebral infarcts and cerebral atrophy are pre-existing conditions diagnosed at the time of the event by CT scan. These will be reported as AEs, as they not part of the SAE term

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Nov-10-2020 07:43:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry : Left Middle Cerebral Artery Infarct	Left Middle Cerebral infarct is the event reported as SAE. Chronic cerebral infarcts and cerebral atrophy are pre-existing conditions diagnosed at the time of the event by CT scan. These will be reported as AEs, as they not part of the SAE term
Nov-09-2020 14:13:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Response satisfies query
Nov-07-2020 18:52:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	SAE RECON:AER#2020413905,Please consider to split the event terms and determine seriousness. If the 2 additional events of chronic cerebellar infarcts and cerebral atrophy are deemed serious, please submit a follow up SAE form.
Nov-05-2020 20:31:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 4: Opened	Multiple concepts in the term LEFT MIDDLE CEREBRAL ARTERY INFARCT, CHRONIC CEREBELLAR INFARCTS AND CEREBRAL ATROPHY. Split the term into LEFT MIDDLE CEREBRAL ARTERY INFARCT and CHRONIC CEREBELLAR INFARCTS and CEREBRAL ATROPHY and report as separate entries.Thank you.
Nov-05-2020 12:42:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-05-2020 12:42:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Left Middle Cerebral Artery I	Transcription Error

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			nfarct, Chronic cerebellar infarcts and cerebral atrophy	
Nov-05-2020 03:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued: Opened	Left middle Cerebral artery Infarct has been recorded correctly. The CRF is missing the events of "chronic cerebellar infarcts and cerebral atrophy" reported in the narrative. If these events are not part of the Med Hx, please update AE log.
Nov-05-2020 03:52:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	Query created in error
Nov-05-2020 03:47:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	Left middle Cerebral artery Infarct has been recorded correctly. The CRF is missing the events of "chronic cerebellar infarcts and cerebral atrophy" reported in the narrative. If these events are not part of the Med Hx, please update AE log. Thank you.
Nov-02-2020 12:22:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Please clarify as term is as it is on the SAE form?
Nov-02-2020 03:18:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Please assess additional reported events on case report: chronic cerebellar infarcts, cerebral atrophy. Kindly revise and update AE log accordingly. Thank you.
Oct-31-2020 17:00:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Term discrepancy considered acceptable by Clinician below.

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Oct-30-2020 13:28:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate date	SAE RECON:For Clinical review
Oct-29-2020 17:08:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Query 1: Answered	Original value is correct
Oct-29-2020 12:56:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020413905,the term was updated to 'Left Middle Cerebral Artery Infarct'in AE CRF while recorded as 'cerebrovascular accident'in Safety database. Please confirm correct term.If safety update is required, please submit a follow-up form.
Oct-28-2020 11:06:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry : Left Middle Cerebral Artery Infarct	New Information
Oct-28-2020 11:04:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry : Cerebrovascular Accident- Left middle cerebral artery infarct	New Information
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Cerebrovasc	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-06-2020 16:38:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-05-2020 12:43:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ongoing
Nov-04-2020 19:13:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify if AE is still ongoing or if it has resolved. If resolved-please enter stop date.
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
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Oct-26-2020 12:49:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	event entered in sdb
Oct-25-2020 14:06:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON 1: Per latest SAE listing event still missing in Safety database report. Please confirm if a follow up AEM form was sent as stated in the previous query response.
Oct-24-2020 16:12:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	SAE RECON: Pending SDB update
Oct-23-2020 14:38:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE reported to Pfizer on 22 Oct 2020.
Oct-23-2020 13:34:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:Cerebrovascular Accident(Onset date:21Oct2020) 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-23-2020 13:33:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Cerebrovascular Accident: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect?	Initial Entry

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			NO	
			Did this serious event result in death?	
			NO	
			Did this serious event require or prolong hospitalization?	
			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			YES	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER If Other, specify:	Initial Entry

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			Pt.68 years old; and 50 pack year history of smoking as risk factors for event.	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-02-2020 13:40:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-02-2020 12:20:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Updated data was sent to the Safety database (30 Oct 2020)
Oct-30-2020 13:24:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON 2: The action taken was updated to DRUG WITHDRAWN in AE CRF, however retained as not applicable in Safety database. Please confirm if a follow up AEM form was sent to update outcome in Safety.
Oct-29-2020 19:04:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-29-2020 17:10:02 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Query 3: Answered	Original value is correct
Oct-29-2020 16:07:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	CLINQUERY: Since action is now noted as 'drug withdrawn' please confirm that a decision has been to permanently discontinue study treatment. If no decision has been made please update to 'not applicable' until such time as a decision is made.

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				Thank you.
Oct-29-2020 12:32:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry: DRUG WITHDRAWN	Initial Entry
Oct-29-2020 10:46:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Decision not yet made - to update as soon as confirmed
Oct-29-2020 10:45:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	It has not yet been decided as to what action will be taken. Data will be updated as soon as a decision has been made
Oct-28-2020 23:49:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY: Apologies but if a decision has NOT been made to discontinue treatment please note the response to this question as 'not applicable'. Thank you.

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-28-2020 11:20:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON 1: The field was left blank. Please confirm action taken for the event cerebrovascular accident.
Oct-28-2020 10:58:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Oct-28-2020 10:58:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Data Entry:	Changed Information
Oct-27-2020 11:21:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020413905 ,action taken was reported as NOT APPLICABLE in AE CRF while Temporarily Withdrawnin Safety database.Please confirm. If safety update is required, please submit a follow up form
Oct-27-2020 11:21:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	to correct query text
Oct-27-2020 11:20:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020373624 ,action taken was reported as NOT APPLICABLE in AE CRF while Temporarily Withdrawnin Safety database.Please confirm. If safety update is required, please submit a follow up form
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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Date	Location	User	Value	Reason
Oct-22-2020 13:07:50 (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-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-03-2020 15:04:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-03-2020 13:15:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-03-2020 13:15:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RECOVERED/ NOT RESOLVED	Transcription Error
Nov-02-2020 13:45:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020413905,outcome was updated to RECOVERING/RESOLVING on AE CRF while reported as Not Recovered/Not Resolved in Safety databae. Please confirm outcome. If safety update is required, please submit a follow-up form
Oct-28-2020 11:07:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	<u>Data Entry:</u> RECOVERING/RESOLVING	New Information
Oct-22-2020 13:07:50 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RECOVERED/ NOT RESOLVED	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Pretoria				
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-22-2020 13:07:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-26-2020 12:40:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2020413905	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-18-2021 18:19:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	The update has been confirmed. Thanks again
Jan-13-2021 10:36:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	A follow up report to the Initial report was submitted on 20 Nov 2020; unit was added to narrative as per previous query
Jan-10-2021 21:14:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	CLINICAL_ Per case narrative, a glucose of 5.5 is reported. However, the unit and normal range are not reported. Kindly clarify the information provided in a FU report. Thank you.
Nov-26-2020 15:08:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	event term updated in SDB. Cerebrovascular disease no longer listed in SDB
Nov-25-2020 14:51:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON:Per latest SAE listing Cerebrovasculat event was added as a separate SAE in SDB aside from 'Left Middle Cerebral Artery

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

				Infarct'. If this is not a separate SAE, please send a follow up AEM form to clarify the event term
Nov-25-2020 14:44:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	SAE RECON:Per latest SAE listing Cerebrovasculat event was added as a separate SAE in SDB aside from 'Left Middle Cerebral Artery Infarct'. If this is not a separate SAE, please send a follow up AEM form to clarify the event term
Nov-23-2020 12:59:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Update SAE term was sent - SAE in log line 1 is the event you are referring to
Nov-23-2020 12:37:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020460756 cerebrovascular accident(onset date:21Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Nov-20-2020 14:13:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Nov-20-2020 13:11:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Unit is confirmed as mmol/L. Initial report with updated information to be faxed again.
Nov-20-2020 02:18:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per case narrative, a glucose of 5.5 is reported. However, the unit and normal range are not reported. Kindly clarify the information provided. Thank you.
Nov-12-2020 10:32:45 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic cerebelar infarcts	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Pretoria				
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4. Start Date Time:

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/23/2020 11:34	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> CT finding	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLV ED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-12-2020 10:32:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cerebral atrophy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/23/2020 11:34	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: CT Findings	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	NO	
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-12-2020 10:33:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Local injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/17/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (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
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (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
Feb-22-2021 14:39:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-22-2021 11:20:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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Feb-22-2021 11:20:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Feb-22-2021 09:53:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Source suggests that no conmeds were given/taken by participants. Please confirm and update CRF if necessary
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-18-2021 11:31:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471135

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-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Medication Error (Type of Medication Error):

Date	Location	User	Value	Reason
Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Start Date:

Date	Location	User	Value	Reason
Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Is the medication error still ongoing?

Date	Location	User	Value	Reason
Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Was a Non-Drug Treatment given?

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090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

8. Did the Medication Error cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

9. Was this medication error associated with any adverse events?

Date	Location	User	Value	Reason
Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

10. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-22-2020 13:11:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
- eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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-22-2020 13:11:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-22-2020 13:11:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-22-2020 13:11:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-22-2020 13:11:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-22-2020 13:11:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
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090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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7. Dose Frequency:

Date	Location	User	Value	Reason
Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Oct-22-2020 13:15:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

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: ---

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

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1. Category:

Date	Location	User	Value	Reason
Oct-22-2020 13:14:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. What is the treatment Identifier?

Date	Location	User	Value	Reason
Oct-22-2020 13:14:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-22-2020 13:14:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Oct-22-2020 13:14:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-22-2020 13:14:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-22-2020 13:14:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

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: ---

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

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1. Transfusion Type:

Date	Location	User	Value	Reason
Oct-22-2020 13:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Date of Transfusion:

Date	Location	User	Value	Reason
Oct-22-2020 13:14:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-30-2020 08:38:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-30-2020 08:38:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-03-2020 14:59:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-03-2020 11:00:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query.
Nov-02-2020 13:39:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Nov-01-2020 12:14:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM 1: Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided. Please check and update accordingly.
Oct-30-2020 20:33:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 08:45:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Oct-30-2020 08:44:44 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	IP discontinued due to SAE. Pt. not

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1247**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject No:** 12471135**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Pretoria		(b) (4), (b) (6)		discontinued from study.
Oct-30-2020 08:38:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Oct-30-2020 08:38:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Oct-30-2020 08:38:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ADVERSE EVENT	Initial Entry
Oct-30-2020 08:35:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Disposition page does not qualify for this adverse event. Lat action taken was drug withdrawn ,AE did not result in death. EOT will be updated.
Oct-29-2020 19:05:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: According to the AE log, the event of Gr 3 left middle cerebral artery infarct resulted in the study drug being withdrawn. Please complete the disposition-treatment CRF and note the subject discontinued due to adverse event. Thank you.

4. Specify Status:

Date	Location	User	Value	Reason
Nov-02-2020 13:39:04 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Pretoria				
Oct-30-2020 08:38:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Left Middle Cerebral Artery Infarcti on.	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-22-2021 14:43:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Feb-22-2021 11:22:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-22-2021 11:22:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) [REDACTED], (4), [REDACTED], (b) (6) [REDACTED]	Data Entry: Feb/1/2021	Transcription Error
Feb-18-2021 17:42:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	Source indicates contact made on 01Feb2021. Kindly confirm and update if required
Feb-16-2021 09:51:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Feb/16/2021	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Feb-22-2021 22:35:45 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Closed	Response satisfies query
Feb-22-2021 11:23:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Feb-18-2021 17:36:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	No data change is observed. Please check and review data as appropriate.
Feb-18-2021 07:30:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-18-2021 07:30:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for V accination 3 Participant is: eligible per other protocol allow ance(s) and confirmed to have r eceived only placebo at Vaccina tion 1/2	Transcription Error
Feb-17-2021 08:43:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-16-2021 09:52:04 (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

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - 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

				visit. Please complete this date.
Feb-16-2021 09:52:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for V accination 3 Participant is: eligible per local/national recom mendations and confirmed to ha ve received only placebo at Vac cination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

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 11:23:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/2/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-22-2021 11:23:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

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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I. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Feb-22-2021 11:23:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

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:

Date	Location	User	Value	Reason
Feb-22-2021 11:23:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-16-2021 09:54:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-16-2021 09:54:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Feb/16/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-16-2021 09:54:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-16-2021 09:54:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-16-2021 09:54:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

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
Feb-16-2021 12:30:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Feb-16-2021 09:55:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-16-2021 12:30:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Feb-16-2021 09:55:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-16-2021 12:32:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-16-2021 12:30:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-16-2021 09:55:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-16-2021 12:30:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Feb-16-2021 09:55:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Feb-16-2021 12:30:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Feb-16-2021 09:55:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-16-2021 09:55:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier: Test:: Choriogonadotropi n Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-16-2021 09:55:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-16-2021 09:55:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-16-2021 09:55:08 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Pretoria

(b) (4), (b) (6)

Header Text: c4591001

Visit: V101_VAX3

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: 12471135

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-16-2021 11:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-16-2021 11:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-16-2021 14:42:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-16-2021 11:37:41 (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-16-2021 11:37:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/16/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-16-2021 14:42:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRKR5Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Feb-18-2021 22:07:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 15:46:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-16-2021 23:03:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7271351;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-16-2021 14:42:03 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : BRKR5Y	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-16-2021 14:42:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRYB2J	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 14:42:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRYB2J	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-16-2021 14:42:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRYB2K	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 14:42:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRYB2K	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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: 12471135

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-16-2021 09:55:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-16-2021 09:55:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-16-2021 10:08:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-16-2021 10:08:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/16/2021	Transcription Error
Feb-16-2021 09:55:48 (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-16-2021 09:55:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-18-2021 15:45:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRKR5R	Transcription Error

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Feb-16-2021 11:40:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRKR5Y	Transcription Error
Feb-16-2021 10:08:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRKR5R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 22:07:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Cl osed	Response satisfies query
Feb-18-2021 15:45:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: A nswered	Transcription Error
Feb-18-2021 15:45:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : BRKR5R	Transcription Error
Feb-16-2021 23:03:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: O pened	DMW7271352;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-16-2021 11:40:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : BRKR5Y	Transcription Error
Feb-16-2021 10:08:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : BRKR5R	Initial Entry

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Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-16-2021 11:41:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-16-2021 11:41:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-16-2021 11:41:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-16-2021 11:41:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/16/2021 10:33	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-16-2021 11:41:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-16-2021 11:41:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-16-2021 11:41:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-16-2021 11:41:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-16-2021 11:41:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-16-2021 11:41:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-16-2021 11:41:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: DATE OF VISIT - 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. Date of Visit

Date	Location	User	Value	Reason
Mar-09-2021 09:09:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Mar/9/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

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3. Collection Date:

Date	Location	User	Value	Reason
Mar-09-2021 09:11:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Mar-09-2021 09:11:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-09-2021 09:11:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-09-2021 09:11:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Mar-09-2021 09:11:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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: 12471135

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
Mar-09-2021 09:11:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-09-2021 09:11:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-09-2021 15:13:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-09-2021 12:38:17 (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.
Mar-09-2021 09:11:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-09-2021 09:11:34 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Mar-09-2021 15:13:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRKRBJ	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 15:13:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRKRBJ	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1247

Subject No: 12471135

Generated By: (b) (4)

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-09-2021 09:12:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-09-2021 10:25:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-09-2021 10:25:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-09-2021 10:25:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/9/2021 09:31	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-09-2021 10:25:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-09-2021 10:25:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Verified

Site No: 1247

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

Subject No: 12471135

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-09-2021 10:25:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-09-2021 10:25:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-09-2021 10:25:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-09-2021 10:25:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Mar-09-2021 10:25:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471135

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
Oct-30-2020 08:38:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-01-2020 07:02:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-01-2020 06:59:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-30-2020 08:38:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/21/2020	Initial Entry
Oct-01-2020 07:02:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/30/2020	Initial Entry
Oct-01-2020 06:59:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/30/2020	Initial Entry

090177e196ae2fc4\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471135

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 12:31:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry