

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/9/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12471244]
2.	Birth Date:	UNK/UNK/2001
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN WHITE
6.	Racial Designation:	

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Oct/9/2020
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: 12471244

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bells Palsy Left facial hemipareses]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2011
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bells Palsy Left facial hemipareses]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bells Palsy Left facial hemipareses]
	Start Date:	Feb/UNK/2018
	Ongoing:	NO End Date: Apr/UNK/2018

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/9/2020
2.	Weight:	[85.0]
3.	Unit:	kg
4.	Height:	[157.0]
5.	Unit:	cm
6.	Body Mass Index:	[34.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/9/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Oct/9/2020
2.	Randomization Number:	[105614]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/9/2020
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	[BM9CWZ]
5.b	Sample ID	[BRSTHK]
5.c	Sample ID	[BRSTKG]

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/9/2020
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	[BM9CWM]
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090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/9/2020 09:53
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

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/29/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/29/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/29/2020
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	[BM9FLH]
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090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/29/2020 10:48
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

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/26/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/26/2020
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	[BM9FWF]
5.b	Sample ID	[BRY9P1]
5.c	Sample ID	[BRY9P2]

090177e196ae2fc6\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: 12471244

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: 12471244

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: 12471244

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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090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

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: 12471244

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: 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: 12471244

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: 12471244 **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: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1247

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

Subject No: 12471244

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: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
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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: 12471244

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	Recurrence of Left Bells Palsy Left facial hemipareses	Feb/11/2021 UNK:UNK	YES	Repeating Pages

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

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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)	[Recurrence of Left Bells Palsy Left facial hemipareses]	Comments
4.	Start Date Time:	Feb/11/2021 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	2	
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	RELATED	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	YES	
12.	Was a Non-Drug Treatment given?	NO	

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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

Subject Initials: ---

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

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

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: 12471244

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR

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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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

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1247

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

Subject No: 12471244

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

1.	What is the medication identifier?	Not 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: 12471244

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.	1	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Prednisone	60	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY
3.	Concomitant Medications Pre-specified:	NO
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).	[Prednisone]
5.	Dose:	[60]
6.	Dose Unit:	mL
7.	Dose Frequency:	QD
8.	Route:	ORAL
9.	Start Date:	Feb/11/2021
10.	Ongoing?	NO End Date: Feb/21/2021

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Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1247

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

Subject No: 12471244

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: RADIATION TREATMENT

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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[eCRF Audit Trail History](#)

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

090177e196ae2fc6\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: 12471244

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: TRANSFUSIONS

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Nov/26/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1247

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

Subject No: 12471244

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: 12471244

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: 12471244

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:	

090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1247

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

Subject No: 12471244

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?	

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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: 12471244

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: 12471244

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: 12471244

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: 12471244

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

Site No: 1247

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

Subject No: 12471244

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: 12471244

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/1/2021
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: 12471244

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

			Comments
1.	Withdrawal of Consent Date :	Not Applicable <hr/> //	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

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
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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: 12471244

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/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1247

Subject No: 12471244

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/3/2021
----	--------------	---

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - 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

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: 12471244

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/3/2021
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: 12471244

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/3/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

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Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

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/3/2021
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	[BRKR0V]
5.b	Sample ID	[BRY9XG]
5.c	Sample ID	[BRY9XH]

090177e196ae2fc6\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: 12471244

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/3/2021
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	[BRKR0D]
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Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1247

Subject No: 12471244

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/3/2021 11:12
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

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Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

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/24/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1247

Subject No: 12471244

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Done //	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

090177e196ae2fc6\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: 12471244

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Visit delayed]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Queries, 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?	YES Date of First Delay: Feb/24/2021 Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC CORTICOSTEROID TREATMENT	
2.	Treatment Name	[]	
3.	Formulation:		
4.	Dose Date Time:	Not Applicable _____ //	Comments
5.	Anatomical Location:		
6.	Body Side:	Not Applicable _____	Comments
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?	Not Applicable _____	Comments

090177e196ae2fc6\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: 12471244

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: 12471244

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: 12471244

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: 12471244

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: 12471244

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: 12471244

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: 12471244

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: 12471244

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/26/2020

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: 12471244

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: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	-------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1247

Subject No: 12471244

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-09-2020 12:48:52 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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	Mar-04-2021 18:02:19 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	
Form	Oct-09-2020 12:49:59 (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: 12471244

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete

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-08-2021 12:49:19 (UTC+02:00) Harare, Pretoria	Haylene Nell (b) (4)	MedHx CRF still frozen, unable to respond

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - 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-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - 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-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - 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
2	Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - 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	Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - 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
4	Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - 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
5	Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - 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
6	Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - 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
7	Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - 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
8	Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - 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
9	Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - 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
10	Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	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, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Feb-24-2021 14:45:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	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, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Feb-24-2021 14:45:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	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, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Feb-24-2021 14:45:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	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, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	Feb-24-2021 14:45:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	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, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
4	Feb-24-2021 14:45:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	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, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Feb-24-2021 14:45:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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-24-2021 14:50:40 (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: 12471244

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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-24-2021 14:50:40 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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
2	Feb-24-2021 14:50:40 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Feb-24-2021 14:50:40 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Feb-24-2021 14:50:40 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Feb-24-2021 14:50:40 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Feb-24-2021 14:50:40 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: TRANSFUSIONS - 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-24-2021 14:51:27 (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: 12471244

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-24-2021 14:51:27 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: TRANSFUSIONS - 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
2	Feb-24-2021 14:51:27 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

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-26-2021 14:42:57 (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: 12471244

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-26-2021 14:42:57 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

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-26-2021 14:42:38 (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: 12471244

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-26-2021 14:42:38 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	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: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Feb-03-2021 16:52:12 (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: 12471244

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-24-2021 15:04:33 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	NB visit delayed
3	Feb-24-2021 15:02:38 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Queries, 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	Mar-03-2021 21:06:12 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [REDACTED]	To be completed when pt comes back for vaccination <hr/> Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Queries, 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	Mar-03-2021 21:06:30 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	To be completed when pt comes back for vaccination <hr/> Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Queries, 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	Mar-03-2021 21:06:49 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6) [Redacted]	To be completed when pt comes back for vaccination <hr/> 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: 12471244

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-03-2021 16:50:58 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated

Affidavit:

N/A

Haylene Nell	Approved	Jan-27-2021 16:48:12 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Dec-08-2020 08:05:37 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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Affidavit:

N/A

Haylene Nell	Approved	Nov-12-2020 21:21:44 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae2fc6\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: 12471244

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
Oct-09-2020 11:05:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 11:05:25 (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: 12471244

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
Oct-09-2020 11:06:05 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Oct/9/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Oct-09-2020 11:05:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12471244	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-09-2020 11:05:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: UNK/UNK/2001	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-09-2020 11:06:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-09-2020 11:06:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-09-2020 11:06:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLACK OR AFRICAN AMERI CAN WHITE	Initial Entry

090177e196ae2fc6\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: 12471244

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-09-2020 12:45:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Oct/9/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1247

Subject No: 12471244

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-09-2020 12:49:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-09-2020 12:49:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-09-2020 12:49:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1.a

Date	Location	User	Value	Reason
Mar-10-2021 15:30:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH N umber: 1 Medical Hi story Term: Bells Palsy Left fa cial hemipareses Start Date: UNK/UNK/2011 Ongoing: NO End Date: UNK/UNK/2011	New Information
Mar-09-2021 15:59:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num ber: 1 Medical Histor y Term: Bells Palsy Start Date: UNK/UNK/2011 Ongoing: NO End Date: UNK/UNK/2011	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Mar-09-2021 15:59:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 15:30:20 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bells Palsy Left facial hemipares	New Information

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Pretoria		(b) (4), (b) (6)	es	
Mar-09-2021 15:59:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bells Palsy	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Mar-09-2021 15:59:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2011	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Mar-09-2021 15:59:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2011	Initial Entry

1.b

Date	Location	User	Value	Reason
Mar-10-2021 15:30:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH N 2 umber: Medical Hi Bells Palsy Left fa story Term: cial hemipareses Start Date: UNK/UNK/2014 Ongoing: NO End Date: UNK/UNK/201 4	New Information
Mar-09-2021 16:00:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 ber: Medical Histor Bells Palsy y Term:	Initial Entry

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

			Start Date: UNK/UNK/2014 Ongoing: NO End Date: UNK/UNK/2014
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1.b Line/MH Number:

Date	Location	User	Value	Reason
Mar-09-2021 16:00:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 15:30:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bells Palsy Left facial hemipareses	New Information
Mar-09-2021 16:00:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bells Palsy	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Mar-09-2021 16:00:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Mar-09-2021 16:00:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

1.c

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Mar-10-2021 15:30:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH N umber: 3 Medical History Term: Bells Palsy Left facial hemipareses Start Date: Feb/UNK/2018 Ongoing: NO End Date: Apr/UNK/2018	New Information
Mar-09-2021 16:00:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Bells Palsy Start Date: Feb/UNK/2018 Ongoing: NO End Date: Apr/UNK/2018	Initial Entry

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Mar-09-2021 16:00:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 15:30:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bells Palsy Left facial hemipares es	New Information
Mar-09-2021 16:00:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bells Palsy	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Mar-09-2021 16:00:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/UNK/2018	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Mar-09-2021 16:00:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Apr/UNK/2018	Initial Entry

090177e196ae2fc6\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: 12471244

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-09-2020 12:50:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1247

Subject No: 12471244

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-09-2020 12:52:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 85.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 157.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:01 (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-09-2020 12:52:01 (UTC+02:00) Harare,	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 34.5	Initial Entry

090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1247

Subject No: 12471244

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

Pretoria				
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7.a

Date	Location	User	Value	Reason
Oct-09-2020 12:52:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 :: Temperature: 36.3 Temperature Unit C : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:01 (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-09-2020 12:52:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2fc6\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: 12471244

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-09-2020 12:52:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-09-2020 12:52:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae2fc6\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: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

Oct-09-2020 12:52:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-09-2020 12:52:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2fc6\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: 12471244

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-09-2020 12:52:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-13-2020 12:47:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 12:45:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-12-2020 12:45:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 105614	Transcription Error
Oct-12-2020 11:15:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	As per Impala, Randomization Number is 105614 . Please review and update as appropriate. (b) (4)
Oct-09-2020 12:52:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 126792	Initial Entry

090177e196ae2fc6\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:** 12471244**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-09-2020 12:52:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-09-2020 12:52:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 16:43:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 12:52:50 (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-09-2020 12:52:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Collection: Oct/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 16:43:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BM9CWZ	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 16:43:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM9CWZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 16:43:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRSTHK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 16:43:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSTHK	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-09-2020 16:43:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRSTKG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 16:43:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRSTKG	Initial Entry

090177e196ae2fc6\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:** 12471244**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-09-2020 12:53:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-09-2020 16:43:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 12:53:01 (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-09-2020 12:53:01 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Collection: Oct/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 16:43:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BM9CWM	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 16:43:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM9CWM	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471244

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-09-2020 12:53:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-09-2020 12:53:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-09-2020 12:53:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-09-2020 12:53:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2020 09:53	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-09-2020 12:53:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-09-2020 12:53:18 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2fc6\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: 12471244

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

Pretoria		(b) (4), (b) (6)	
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7. Route:

Date	Location	User	Value	Reason
Oct-09-2020 12:53:18 (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-09-2020 12:53:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-09-2020 12:53:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fc6\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: 12471244

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-09-2020 12:53:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

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-29-2020 15:03:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/29/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Oct-29-2020 15:03:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/29/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-29-2020 15:03:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 :: Temperature: 36.3 Temperature Unit C : Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-29-2020 15:03:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-29-2020 15:03:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-29-2020 15:03:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-29-2020 15:03:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

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-29-2020 15:03:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-29-2020 15:03:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-29-2020 15:03:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/29/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-29-2020 15:03:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-29-2020 15:03:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

Oct-29-2020 15:03:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:03:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-29-2020 15:03:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-29-2020 15:03:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2fc6\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:** 12471244**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-29-2020 15:03:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-29-2020 15:03:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-29-2020 17:46:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-29-2020 15:03:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-29-2020 15:03:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-29-2020 17:46:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9FLH	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-29-2020 17:46:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM9FLH	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-29-2020 15:04:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-29-2020 15:04:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-29-2020 15:04:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-29-2020 15:04:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/29/2020 10:48	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-29-2020 15:04:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-29-2020 15:04:14 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2fc6\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: 12471244

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

Pretoria		(b) (4), (b) (6)	
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7. Route:

Date	Location	User	Value	Reason
Oct-29-2020 15:04:14 (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-29-2020 15:04:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-29-2020 15:04:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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: 12471244

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
Dec-08-2020 21:46:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-08-2020 08:05:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Dec-08-2020 08:05:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/26/2020	Initial Entry
Dec-05-2020 00:04:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLIN: Subject study vaccination 2 occurred on 29/Oct /2020. V3 is expected. Please clarify disposition of subject and if V3 is planned to occur.

090177e196ae2fc6\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:** 12471244**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-08-2020 08:05:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-08-2020 08:05:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-17-2020 14:28:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-09-2020 11:51:16 (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.
Dec-08-2020 08:05:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-08-2020 08:05:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/26/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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5.a

Date	Location	User	Value	Reason
Dec-17-2020 14:28:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BM9FWF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 14:28:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM9FWF	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-17-2020 14:29:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRY9P1	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 14:29:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRY9P1	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-17-2020 14:29:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRY9P2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 14:29:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRY9P2	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1247

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-24-2021 14:44:11 (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: 12471244

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Feb-24-2021 14:44:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-24-2021 14:44:11 (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
Mar-10-2021 16:05:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-10-2021 16:03:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Site to request notes from hospital
Mar-10-2021 15:49:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	clinical: Thanks, confirming last episode refers to current one not the one in 2018? Pls advise if subject had any testing done eg blood work, radiological imaging?
Mar-10-2021 15:38:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	MedHx terms updated. Patient was diagnosed by neurology department of Tygerberg Hospital in 2011, 2014, and

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				this last episode. Patient was treated with cortisone tablets for each event. All events resolved completely apart from the last one.
Mar-09-2021 17:32:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	clinical: Thanks, but pls update MedHx diagnoses to indicate laterality of each episode. Pls provide details on how diagnosis was made, was subject tested for Lyme disease, any details on prior treatment and if prior episodes resolved completely.
Mar-09-2021 16:01:42 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Medical history page updated
Mar-09-2021 15:57:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	clinical: please add history regarding previous episode of Bell's to MedHx CRF if it predated enrollment. MedHx CRF unlocked for you. Did prior episode of Bell's resolve completely?
Mar-09-2021 15:54:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Mar-09-2021 15:54:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Recurrence of Left Bells Palsy Left facial hemipareses	New Information

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Site No: 1247

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Generated By: (b) (4)

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Subject Initials: ---

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Mar-08-2021 19:51:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	clinical: confirmed with DM, this should be unfrozen now. Thanks
Mar-08-2021 12:51:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Haylene Nell (b) (4)	Query 3: Answered	MedHX CRF still frozen
Mar-07-2021 19:52:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	clinical: please update MedHx CRF with info on past hx Bell's including laterality. CRF unlocked and unfrozen but will be relocked soon. If you are having difficulty, please advise. Thanks
Mar-07-2021 19:51:54 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	clinical: reissued.
Mar-04-2021 17:01:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	clinical: confirmed with DM, CRF is unfrozen and unlocked now. Thanks!
Mar-04-2021 12:20:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The page is still frozen Kind regards,
Mar-02-2021 17:03:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	closed due to duplicated inquiry. MH still needs to be updated
Mar-02-2021 15:36:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	clinical: Thanks, but please also update MedHx CRF with info on past hx Bell's including laterality. CRF unlocked for you.

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1247**Subject No:** 12471244**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

Mar-02-2021 08:29:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Recurrence of Left Bells Palsy	At study entrance this Left Bells palsy was not active and did not pose a risk as per the judgement of the investigator
Mar-02-2021 07:59:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Mar-02-2021 07:59:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-02-2021 07:59:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Worsening of Left Bells Palsy	New Information
Feb-26-2021 17:04:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	clinical: please indicate laterality for Bell's palsy in AE term and also when update MedHx CRF. Thanks
Feb-26-2021 16:41:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Reissued:Opened	GPD Clin: MH term unlocked, please kindly add missing term into the MH as per previous query response. Thanks
Feb-26-2021 13:01:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Please unlock medical history page in order to update data
Feb-25-2021 21:37:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Worsening of Bells Palsy was reported as AE, however no corresponding event of Bell's Palsy is reported on the MH

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Visit: Logs - Unscheduled

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Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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

Subject Initials: ---

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

				eCRF page. Please review and update MH accordingly, else clarify. Thanks
Feb-24-2021 14:44:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Worsening of Bells Palsy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-24-2021 14:44:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-09-2021 15:57:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-09-2021 15:55:00 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirmed as per source notes still ongoing
Mar-08-2021 18:49:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls confirm AE ongoing or update CRF with end date, thanks
Feb-24-2021 14:44:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-24-2021 14:44:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

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If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-24-2021 14:44:11 (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
Feb-24-2021 14:44:11 (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
Mar-02-2021 15:34:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-02-2021 07:47:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Bells Palsy worsened right after the vaccination visit 101
Feb-26-2021 17:07:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: please advise as to why AE determined to be 'related' Thanks
Feb-24-2021 14:44:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Form Status: Data Complete

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Feb-24-2021 14:44:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-24-2021 14:44:11 (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-24-2021 14:44:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-24-2021 14:44:11 (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-24-2021 14:44:11 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - 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-24-2021 14:44:36 (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
Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Start Date:

Date	Location	User	Value	Reason
Feb-24-2021 14:44:36 (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
Feb-24-2021 14:44:36 (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
Feb-24-2021 14:44:36 (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
Feb-24-2021 14:44:36 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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Pretoria		(b) (4), (b) (6)	
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7. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Did the Medication Error cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Was this medication error associated with any adverse events?

Date	Location	User	Value	Reason
Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-24-2021 14:44:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc6\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, Verified

Site No: 1247

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

Subject No: 12471244

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
Feb-24-2021 14:45:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-24-2021 14:45:12 (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
Feb-24-2021 14:45:12 (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
Feb-24-2021 14:45:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Feb-24-2021 14:45:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-24-2021 14:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

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
Feb-24-2021 14:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-24-2021 14:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONCOMITANT IMMUNOSU PPRESSIVE THERAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-24-2021 14:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	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
Feb-26-2021 16:37:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	Response satisfies query
Feb-26-2021 13:02:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirmed that prednisone was used for Bells palsy
Feb-25-2021 23:17:19 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Can you please confirm the reason for prednisone intake was Bells palsy? Thank you

090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

Feb-24-2021 14:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Prednisone	Initial Entry
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5. Dose:

Date	Location	User	Value	Reason
Feb-24-2021 14:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 60	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Feb-24-2021 14:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mL	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-24-2021 14:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Feb-24-2021 14:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Feb-24-2021 14:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
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090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

Feb-24-2021 14:50:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Feb/21/2021	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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-24-2021 14:50:40 (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
Feb-24-2021 14:50:40 (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
Feb-24-2021 14:50:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Feb-24-2021 14:50:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Feb-24-2021 14:50:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 14:50:40 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc6\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: 12471244

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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

Pretoria

(b) (4), (b) (6)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: TRANSFUSIONS - 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. Transfusion Type:

Date	Location	User	Value	Reason
Feb-24-2021 14:51:27 (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
Feb-24-2021 14:51:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fc6\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, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

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
Dec-09-2020 06:57:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/26/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-09-2020 06:57:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-10-2020 00:25:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-09-2020 06:57:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Dec-09-2020 06:57:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry
Dec-08-2020 21:46:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLIN: Subject has completed vaccinations 1 and 2 and visit 3 has been completed thus please complete the EOT CRF. Thank you.

090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

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-03-2021 16:50:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/1/2021	Initial Entry

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1247**Subject No:** 12471244**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)***1. Select appropriate response - Is participant willing to return for Vaccination 3?***

Date	Location	User	Value	Reason
Feb-06-2021 12:18:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 11:58:54 (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-03-2021 16:51:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-03-2021 16:51:09 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible per other protocol al lowance(s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

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-06-2021 12:18:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/1/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-06-2021 12:18:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Feb-26-2021 14:42:57 (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: 12471244

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-26-2021 14:42:38 (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: 12471244

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-03-2021 16:51:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Feb/3/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER 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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I. Consent Was:

Date	Location	User	Value	Reason
Feb-03-2021 16:51:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/3/2021	Initial Entry

090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

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: 12471244

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-03-2021 16:52:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-03-2021 16:52:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-03-2021 16:52:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fc6\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: 12471244

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-03-2021 16:53:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-03-2021 16:53:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-03-2021 16:53:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-03-2021 16:53:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-03-2021 16:53:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae2fc6\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: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

Feb-03-2021 16:53:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 16:53:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-03-2021 16:53:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-03-2021 16:53:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2fc6\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: 12471244

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-03-2021 16:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-03-2021 16:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 17:11:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 11:32:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-03-2021 16:53:28 (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-03-2021 16:53:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/3/2021	Initial Entry

090177e196ae2fc6\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: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Feb-04-2021 17:11:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRKR0V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 17:11:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRKR0V	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-04-2021 17:11:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRY9XG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 17:11:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRY9XG	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-04-2021 17:11:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRY9XH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 17:11:55 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRY9XH	Initial Entry

090177e196ae2fc6\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: 12471244

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-03-2021 16:53:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-03-2021 16:53:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-04-2021 17:12:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-04-2021 11:32:20 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-03-2021 16:53:56 (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-03-2021 16:53:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/3/2021	Initial Entry

090177e196ae2fc6\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: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Feb-04-2021 17:12:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRKR0D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-04-2021 17:12:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRKR0D	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1247

Subject No: 12471244

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-03-2021 16:54:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-03-2021 16:54:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-03-2021 16:54:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-03-2021 16:54:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021 11:12	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-03-2021 16:54:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-03-2021 16:54:41 (UTC+02:00) Harare,	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2fc6\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: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

Pretoria		(b) (4), (b) (6)	
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7. Route:

Date	Location	User	Value	Reason
Feb-03-2021 16:54:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-03-2021 16:54:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-03-2021 16:54:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-03-2021 16:54:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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-03-2021 16:54:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2fc6\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: 12471244

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-24-2021 15:01:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/24/2021	Initial Entry

Header Text: c4591001**Visit:** V102_VAX4**Form Version:** 14-Jan-2021 02:21**Site No:** 1247**Subject No:** 12471244**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-24-2021 15:02:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-24-2021 15:07:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defi ned Identifier : 113 Test:: Choriogonadotro pin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry
Feb-24-2021 15:02:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defi ned Identifier : Test:: Choriogonadotro pin Beta_PX113 Result:: Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-24-2021 15:07:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
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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, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

Feb-24-2021 15:02:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry
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6.a Not Done:

Date	Location	User	Value	Reason
Feb-24-2021 15:07:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

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, Frozen, Verified

Site No: 1247

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

Subject No: 12471244

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-24-2021 15:05:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-24-2021 15:05:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-24-2021 15:05:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 15:05:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Visit delayed	Initial Entry

090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Queries, 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-04-2021 11:12:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	Review after temporary delay is completed
Feb-24-2021 15:06:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-24-2021 15:06:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First Delay: Feb/24/2021 Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC CORTICOSTEROID TREATMENT	Transcription Error
Feb-24-2021 15:05:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Was there a temporary delay of vaccination?' is marked as Yes and 'Date of First Delay' is not entered. Please review and update as appropriate.
Feb-24-2021 15:05:36 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC CORTICOSTEROID TREATMENT	Initial Entry

4. Dose Date Time:

090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1247

Subject No: 12471244

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Queries, 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
Mar-10-2021 18:17:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	To be checked about the status after 28days
Mar-04-2021 09:39:47 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Candidate	DMW7592439;Dose Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Mar-03-2021 21:06:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : Not Applicable	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-03-2021 21:06:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Mar-03-2021 21:06:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae2fc6\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: 12471244

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
Dec-09-2020 06:57:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-09-2020 12:52:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-09-2020 12:49:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-09-2020 06:57:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/26/2020	Initial Entry
Oct-09-2020 12:52:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/9/2020	Initial Entry
Oct-09-2020 12:49:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/9/2020	Initial Entry

090177e196ae2fc6\Final\Final On: 01-Apr-2021 03:51 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1247

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

Subject No: 12471244

Subject Initials: ---

Generated By: (b) (4)

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-11-2020 10:57:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Click Here to Enable	Initial Entry