

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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[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: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/25/2020
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Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12301025]
2.	Birth Date:	UNK/UNK/1946
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/25/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Sep/25/2020
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: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bilateral lens replacement]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tonsillectomy]
	Start Date:	UNK/UNK/1960
	Ongoing:	NO End Date: UNK/UNK/1960
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Inguinal Hernia Repair]
	Start Date:	UNK/UNK/1995
	Ongoing:	NO End Date: UNK/UNK/1995

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Inguinal Hernia Repair]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Laparotomy for tumour excision]
	Start Date:	Oct/27/2014
	Ongoing:	NO End Date: Oct/27/2014
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastric Carcinoma]
	Start Date:	Oct/UNK/2014
	Ongoing:	NO End Date: Oct/27/2014
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chemotherapy]
	Start Date:	Feb/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2016

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
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Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/25/2020
2.	Weight:	[76.4]
3.	Unit:	kg
4.	Height:	[175.0]
5.	Unit:	cm
6.	Body Mass Index:	[24.9]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.2]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/25/2020
2.	Randomization Number:	[265253]
3.	Randomization Group:	[]

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/25/2020
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	[BRSD3V]
5.b	Sample ID	[BRSD48]
5.c	Sample ID	[BM97FF]

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/25/2020
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	[BM97F0]
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090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/25/2020 10:47
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

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/16/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR810J]
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090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[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/16/2020 12:02
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

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/13/2020
2.	Erroneous Visit	

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/13/2020
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	[BRSC21]
5.b	Sample ID	[BRSC1S]
5.c	Sample ID	[BR8153]

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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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090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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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090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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	[]
----	-----------	-----

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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: 28-Mar-2021 02:35

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 28-Mar-2021 02:23

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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 Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Mar/03/2021

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Mar/03/2021

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Unplanned Assessments

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

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Mar/03/2021

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/3/2021 Contact Outcome: VISIT ARRANGED
3.	Comments:	[]

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Mar/03/2021

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Mar/3/2021
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: C4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Mar/03/2021**Form Version:** 20-Feb-2021 02:13**Site No:** 1230**Subject No:** 12301025**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1230) Tamboti Medical Centre**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Form Comments](#)
[eCRF Audit Trail History](#)**Unplanned Assessment Of Local Reaction**

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Injection Site Location	Not Applicable _____	Comments
3.	Injection Site Body Side:	Not Applicable _____	Comments

Reaction

4.a	Reaction:	REDNESS	
	Reaction Present:	Not Applicable _____	Comments
4.b	Reaction:	SWELLING	
	Reaction Present:	Not Applicable _____	Comments

Symptom

5.a	Symptom:	PAIN AT INJECTION SITE	
	Symptom Present:	Not Applicable _____	Comments
5.b	Symptom:	FATIGUE/TIREDNESS	
	Symptom Present:	Not Applicable _____	Comments
5.c	Symptom:	HEADACHE	
	Symptom Present:	Not Applicable _____	Comments
5.d	Symptom:	VOMITING	
	Symptom Present:	Not Applicable _____	Comments

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Mar/03/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.e	Symptom:	DIARRHEA	
	Symptom Present:	Not Applicable	Comments
5.f	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Symptom Present:	Not Applicable	Comments
5.g	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Symptom Present:	Not Applicable	Comments
5.h	Symptom:	CHILLS	
	Symptom Present:	Not Applicable	Comments

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Nov/13/2020
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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 28-Mar-2021 02:28

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Vital Signs

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

Vital Signs Details

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

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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?	

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Contact Outcome

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Informed Consent - Asymptomatic Surveillance

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/22/2021
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, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Penile Intra Epithelial Neoplasia	Nov/6/2020 16:24	YES	Repeating Pages
2.	ADVERSE EVENT	2	PENILE INVASIVE MODERATELY DIFFERENTIAL KERATINIZING SQUAMOUS CELL CARCINOMA	Nov/6/2020 16:24	YES	Repeating Pages

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Penile Intra Epithelial Neoplasia]
4.	Start Date Time:	Nov/6/2020 16:24
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
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

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Neoplasia]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020451162]

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[PENILE INVASIVE MODERATELY DIFFERENTIAL KERATINIZING SQUAMOUS CELL CARCINOMA]
4.	Start Date Time:	Nov/6/2020 16:24
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [CANCER]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
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).	[]
5.	Date:	//

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

Concomitant Medications

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

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: C4591001

Visit: UNPLANNED_BOOSTER_CONTACT - **Form:** DATE OF VISIT

Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Header Text: C4591001

Visit: UNPLANNED_BOOSTER_CONTACT - **Form:** BOOSTER DOSE TRIGGER FORM
Unscheduled

Form Version: 20-Feb-2021 02:20

Form Status: Not Started

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Booster Dose Trigger Form

1.	Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit?	
----	--	--

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Treatment Unblinded

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

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/13/2020

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[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, Signed, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Leon Fouche	Approved	Mar-24-2021 18:25:12 (UTC+02:00) Harare, Pretoria	BOOK	Signed

Affidavit:

By my dated signature below, I, LeonFouche, 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.

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Sep-25-2020 11:39:00 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Mar/03/2021

Form Version: 20-Feb-2021 02:13

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
1	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
2	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
3	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
4.a	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
4.b	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
5.a	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
5.b	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
5.c	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
5.d	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
5.e	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
5 f	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
5.g	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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Item	Date	User	Comment
5 h	Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Leon Fouche	Approved	Mar-24-2021 18:25:12 (UTC+02:00) Harare, Pretoria	BOOK	Signed

Affidavit:

By my dated signature below, I, LeonFouche, 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	Mar-24-2021 18:18:50 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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Affidavit:

N/A

Leon Fouche	Approved	Mar-23-2021 12:56:48 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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Affidavit:

By my dated signature below, I, LeonFouche, 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	Jan-27-2021 16:26:59 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Leon Fouche	Approved	Jan-22-2021 16:03:34 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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Affidavit:

By my dated signature below, I, LeonFouche, 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	Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria		Edit - All signatures invalidated
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Affidavit:

N/A

Leon Fouche	Approved	Nov-15-2020 23:03:38 (UTC+02:00) Harare, Pretoria	BOOK	Signed
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Affidavit:

By my dated signature below, I, LeonFouche, 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.

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-25-2020 11:37:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 11:37:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-25-2020 11:38:10 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: OBTAINED Date Written Consent Obtained Sep/25/2020	Initial Entry

Header Text: C4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Subject ID

Date	Location	User	Value	Reason
Sep-25-2020 11:37:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 12301025	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-30-2020 21:36:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DM001_03
Sep-30-2020 14:49:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-30-2020 14:49:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1946	Transcription Error
Sep-30-2020 12:45:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DMW4821239;Site is in Germany or South Africa, however Date of Birth is complete.
Sep-28-2020 16:02:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Candidate	DMW4818977;Site is in Germany or South Africa, however Date of Birth is complete.
Sep-25-2020 11:37:45 (UTC+02:00) Harare,	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6) 1946	Enrollment Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Pretoria				
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3. Sex:

Date	Location	User	Value	Reason
Sep-25-2020 11:38:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-25-2020 11:38:32 (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
Sep-25-2020 11:38:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-25-2020 11:38:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-25-2020 11:39:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-25-2020 11:39:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-25-2020 11:39:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1.a

Date	Location	User	Value	Reason
Sep-25-2020 11:40:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Bilateral lens replacement Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2010	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 11:40:49 (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
Sep-25-2020 11:40:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilateral lens replacement	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 11:40:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.a Ongoing:

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-25-2020 11:40:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-25-2020 11:41:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Tonsillectomy Term: Start Date: UNK/UNK/1960 0 Ongoing: NO End Date: UNK/UNK/ 1960	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 11:41:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 11:41:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Tonsillectomy	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 11:41:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1960	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 11:41:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: UNK/UNK/1960	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-25-2020 11:42:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number 3 : Medical History T Hypertension erm: Start Date: UNK/UNK/2 007	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

			Ongoing:	YES	
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 11:42:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 11:42:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Hypertension	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 11:42:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2007	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 11:42:33 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-25-2020 11:44:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Numb 4 er: Medical Histor Inguinal Hernia y Term: Repair	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

			Start Date: UNK/UNK/1995 Ongoing: NO End Date: UNK/UNK/1995
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I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 11:44:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 11:44:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inguinal Hernia Repair	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 11:44:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1995	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 11:44:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1995	Initial Entry

I.e

Date	Location	User	Value	Reason
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090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Sep-25-2020 11:44:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Inguinal Hernia Repair Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	Initial Entry
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090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 11:44:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 11:44:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Inguinal Hernia Repair	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 11:44:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2005	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 11:44:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: UNK/UNK/2005	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-25-2020 12:04:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Line/MH N 6 umber: Medical His Laparotomy for tu tory Term: mour excision Start Date: Oct/27/2014	Transcription Error

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

			Ongoing: NO End Date: Oct/27/2014	
Sep-25-2020 11:49:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu mber: 6 Medical History Term: Laparotomy tumor excision Start Date: Oct/27/2014 Ongoing: NO End Date: Oct/27/2014	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

I.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 11:49:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 12:04:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Laparotomy for tumour excision	Transcription Error
Sep-25-2020 11:49:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Laparotomy tumour excision	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 11:49:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Oct/27/2014	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 11:49:35 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: Oct/27/2014	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-25-2020 12:00:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 7	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

			Medical History Term: Gastric Carcinoma Start Date: Oct/UNK/2014 Ongoing: NO End Date: Oct/27/2014
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I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 12:00:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 12:00:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gastric Carcinoma	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 12:00:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/UNK/2014	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 12:00:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Oct/27/2014	Initial Entry

I.h

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-25-2020 12:01:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Chemotherapy Term: Start Date: Feb/UNK/2015 Ongoing: NO End Date: UNK/UNK/ 2016	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 12:01:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 12:01:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chemotherapy	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 12:01:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/UNK/2015	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 12:01:17 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2016	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Date	Location	User	Value	Reason
Sep-25-2020 12:02:58 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	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: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date:

Date	Location	User	Value	Reason
Sep-25-2020 12:03:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-25-2020 12:03:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 76.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-25-2020 12:03:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-25-2020 12:03:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 175.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-25-2020 12:03:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-25-2020 12:03:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 24.9	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-25-2020 12:03:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 36.2 Temperature Unit: C Temperature Locati on:: FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-25-2020 12:03:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-25-2020 12:03:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 36.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-25-2020 12:03:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C	Initial Entry

7.a Temperature Location:

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-25-2020 12:03:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	<u>Data Entry:</u> FOREHEAD	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-25-2020 12:04:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Sep/25/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-25-2020 12:04:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: 265253	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Sep-25-2020 12:07:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-25-2020 12:07:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-25-2020 12:07:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-25-2020 12:05:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSD3V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 12:05:25 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSD3V	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b

Date	Location	User	Value	Reason
Sep-25-2020 12:05:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSD48	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 12:05:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSD48	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-28-2020 16:40:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: Sample ID: BM97FF	Initial Entry
Sep-28-2020 16:39:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Sep-25-2020 12:05:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM97FF	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.c Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 21:34:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_06
Sep-28-2020 16:40:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : BM97 FF	Initial Entry
Sep-28-2020 16:39:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-28-2020 16:39:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Transcription Error
Sep-28-2020 12:43:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4819006;The Barcode BM97FF is recorded for two subjects 12301024 and 12301025. Two different subjects can not have same barcodes. Please review and update as appropriate.
Sep-25-2020 12:05:52 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : BM97 FF	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Sep-25-2020 12:12:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-25-2020 12:12:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-25-2020 12:12:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-25-2020 12:12:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-25-2020 12:12:31 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-25-2020 12:12:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM97F0	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 12:12:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: BM97F0	Initial Entry

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-25-2020 12:13:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-25-2020 12:13:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-25-2020 12:13:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-24-2021 18:18:50 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020 10:47	Transcription Error
Sep-25-2020 12:13:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020 11:21	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-25-2020 12:13:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

6. Body Side:

Date	Location	User	Value	Reason
Sep-25-2020 12:13:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-25-2020 12:13:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-25-2020 12:13:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 12:13:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-25-2020 12:13:39 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-16-2020 12:36:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Oct/16/2020	Initial Entry

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FE VE R N O Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
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090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic sy mptoms present on the las t day the Subject Diary wa s completed?: NO	Initial Entry
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?: NO	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.c Symptom:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.d Symptom:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.e Symptom:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.f Symptom:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.g Symptom:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.h Symptom:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT P AIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactio NO ns present on the last day the Subject Diary was co mpleted?:	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction PAIN A :: T INJE CTION SITE Were injection site rea NO ctions present on the l ast day the Subject Di ary was completed?:	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 12:37:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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I. Date:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-16-2020 12:37:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.6 Temperature Unit: C Temperature Locati on:: FOREHE AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	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: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Oct-16-2020 15:04:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-16-2020 15:04:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-16-2020 15:05:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-16-2020 15:04:56 (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.
Oct-16-2020 15:04:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 15:05:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR810J	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 15:05:32 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR810J	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-16-2020 12:37:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-16-2020 12:37:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020 12:02	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Oct-16-2020 12:37:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Oct-16-2020 12:37:57 (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-16-2020 12:37:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 12:37:57 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-14-2020 16:16:08 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/13/2020	Initial Entry

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R N O Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			GU E NO Were fever or systemic symptoms present on the last day the Subject Diary was completed?:
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2.b Symptom:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.c Symptom:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.f Symptom:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MUSCLE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.h

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOI NT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-14-2020 16:17:04 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (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, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Data Origin

Date	Location	User	Value	Reason
Nov-14-2020 16:18:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-14-2020 16:18:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-14-2020 16:18:21 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-14-2020 16:17:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSC21	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-14-2020 16:17:30 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSC21	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (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, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Nov-14-2020 16:17:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRSC1S	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Nov-14-2020 16:17:48 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRSC1S	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-14-2020 16:18:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR8153	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-14-2020 16:18:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR8153	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Mar/03/2021

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-04-2021 13:27:07 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/3/2021	Initial Entry

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Mar/03/2021

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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I. Assessments

Date	Location	User	Value	Reason
Mar-04-2021 13:28:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-04-2021 13:27:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Mar-04-2021 13:27:23 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Mar/03/2021

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Contact Type:

Date	Location	User	Value	Reason
Mar-04-2021 13:28:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-08-2021 12:46:15 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Data updated
Mar-04-2021 13:28:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Mar-04-2021 13:28:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Mar/3/2021 Contact Outcome: VISIT ARRANGED	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Mar/03/2021

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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I. Date:

Date	Location	User	Value	Reason
Mar-04-2021 13:29:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/3/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-04-2021 13:29:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.7 Temperature Unit: C Temperature Locati on:: FOREHE AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Mar-04-2021 13:29:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Mar-04-2021 13:29:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Mar-04-2021 13:29:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on
Mar/03/2021

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Mar-04-2021 13:29:53 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FOREHEAD	Initial Entry

Header Text: C4591001**Visit:** Unplanned 1 - Unscheduled Visit on Mar/03/2021**Form Version:** 20-Feb-2021 02:13**Site No:** 1230**Subject No:** 12301025**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1230) Tamboti Medical Centre**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Mar-05-2021 23:10:12 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-05-2021 17:09:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PARTICIPANT CAME FOR FOLLOW UP ON SAE. NO SYMPTOMS REPORTED
Mar-05-2021 12:51:06 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7598049;Date of Assessment is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Injection Site Location

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Mar/03/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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4.a

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: Not Applicabl e Reaction Present Not Applicabl :: e	Initial Entry

4.a Reaction:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4.a Reaction Present:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4.b

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: Not Applicabl e Reaction Present Not Applicabl :: e	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Mar/03/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

4.b Reaction:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable	Initial Entry

5.a Symptom:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Mar/03/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	Symptom:: Not Applicable Symptom Present:: Not Applicable	
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5.b Symptom:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable Symptom Present:: Not Applicable	Initial Entry

5.c Symptom:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Mar/03/2021

Form Version: 20-Feb-2021 02:13

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

5.d

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable	Initial Entry

5.d Symptom:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Mar/03/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.e Symptom:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable	Initial Entry

5.f Symptom:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Symptom Present:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Unplanned 1 - Unscheduled Visit on Mar/03/2021

Form Version: 20-Feb-2021 02:13

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

(UTC+02:00) Harare, Pretoria		(b) (4), (b) (6)	Symptom:: Not Applicable Symptom Present:: Not Applicable	
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5.g Symptom:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Symptom Present:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable Symptom Present:: Not Applicable	Initial Entry

5.h Symptom:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Symptom Present:

Date	Location	User	Value	Reason
Mar-04-2021 13:30:51 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-14-2020 16:18:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-14-2020 16:18:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-14-2020 16:18:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (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, Locked, Frozen, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-27-2021 16:26:59 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2021	Initial Entry

Header Text: C4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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

Date	Location	User	Value	Reason
Jan-27-2021 16:27:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-27-2021 16:27:16 (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.
Jan-27-2021 16:27:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

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Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Category:

Date	Location	User	Value	Reason
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-14-2020 16:43:37 (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
Jan-22-2021 13:36:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-22-2021 09:18:40 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Yes new diagnosis added. No prior diagnosis of other Penile Dysplasia
Jan-20-2021 18:15:14 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	clinical: pls confirm this is a new diagnosis for subject and has no prior hx of dysplasia. Thanks
Dec-03-2020 19:56:49 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	Further clarifications are being addressed through CRA.
Nov-25-2020 13:54:18 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	As per Treating Physician penile intraepithelial neoplasia was noted as high grade.

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Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1230**Subject No:** 12301025**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1230) Tamboti Medical Centre**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54

Nov-24-2020 22:17:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Reissued:Opened	GPD Clin: Cancers that haven't invaded beyond epithelium of penis are known as carcinoma in situ (CIS) or penile intraepithelial neoplasia. Please consult with PI update term and submit SAE FU report, as applicable, else clarify in query response. Thanks
Nov-24-2020 08:30:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not benign and not described as in-situ.
Nov-21-2020 00:26:38 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: per data in safety database participant was diagnosed with "High grade neoplasia", while eCRF verbatim is "Intra Epithelial Neoplasia". Please confirm if participant has benign or in-situ penile neoplasm? Thanks
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Penile Intra Epithelial Neoplasia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/6/2020 16:24	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

		(b) (4), (b) (6)	
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-15-2020 13:01:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Penile Intra Epithelial Neoplasia : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birt	Initial Entry

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Header Text: C4591001

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Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

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			h defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability /incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES	
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8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-24-2020 17:42:44 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	closed based on site's response

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Header Text: C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1230**Subject No:** 12301025**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1230) Tamboti Medical Centre**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54

Nov-24-2020 07:35:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 1: Answered	None noted in source.
Nov-21-2020 00:28:46 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Please confirm if participant had any abnormalities that could have been suggestive for Intra Epithelial Neoplasia at baseline and update MH eCRF page, as applicable. Thanks
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Neoplasia	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESO LVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-14-2020 16:43:37 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-15-2020 13:01:16 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020451162	Initial Entry

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Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Category:

Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-22-2021 19:18:13 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	Response satisfies query
Jan-22-2021 09:25:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Updated to PENILE INVASIVE MODERATELY DIFFERENTIAL KERATINIZING SQUAMOUS CELL CARCINOMA
Jan-22-2021 09:25:27 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PENILE INVASIVE MODERA TELY DIFFERENTIAL KERA TINIZING SQUAMOUS CELL CARCINOMA	Updated to PENILE INVASIVE MODERATELY DIFFERENTIAL KERATINIZING SQUAMOUS CELL CARCINOMA
Jan-19-2021 16:47:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Can you please adjust the term "INVASIVE MODERATELY DIFFERENTIAL

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

				KERATINIZING SQUAMOUS CELL CARCINOMA" to add anatomical location/organ? Thank you
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: INVASIVE MODERATELY DIFFERENTIAL KERATINIZING SQUAMOUS CELL CARCINOMA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/6/2020 16:24	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-15-2021 10:35:29 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Transcription Error
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: CANCER	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

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Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-15-2021 10:25:24 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae303e\Final\Final On: 01-Apr-2021 04:05 (GMT)

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-27-2021 16:27:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-27-2021 16:27:41 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1230

Subject No: 12301025

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1230) Tamboti Medical Centre

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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1. Subject Status

Date	Location	User	Value	Reason
Nov-14-2020 16:18:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-25-2020 12:04:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-25-2020 11:39:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-14-2020 16:18:43 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/13/2020	Initial Entry
Sep-25-2020 12:04:26 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/25/2020	Initial Entry
Sep-25-2020 11:39:28 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/25/2020	Initial Entry

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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, Signed, Verified

Site No: 1230

Site Name: (1230) Tamboti Medical Centre

Subject No: 12301025

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-06-2020 14:29:56 (UTC+02:00) Harare, Pretoria	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Click Here to Enable	Initial Entry