Essential Documents Activity

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1. NAME AND ADDRESS OF INVESTIGATOR Dr. KT MNGADI, CAPRISA, ETHEKWINI CRS, 3 RICHARDS ROAD, BEREA, JOHANNESBURG,4001

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select **one** of the following.)*

Curriculum Vitae | Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED

CONTINUATION PAGE for Item 3

Name of Medical School, Hospital, or Other Research Facility			
CAPRISA			
Address 1 ETHEKWINI CRS, 3 RICHARDS ROAD		Address 2	
City BEREA	State/Province/Region JOHANNESBURG	Country SOUTH AFRICA	ZIP or Postal Code 4001

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY

CONTINUATION PAGE for Item 4

Name of Clinical Laboratory Facility			
Address 1 ETHEKWINI CRS, 3 RICHARDS ROAD		Address 2 ETHEKWINI CRS, 3 RICHARDS ROAD	
City BEREA	State/Province/Region JOHANNESBURG	Country SOUTH AFRICA	ZIP or Postal Code

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES)

CONTINUATION PAGE for Item 5

Name of IRB			
THE BIOMEDICAL RESEARCH ETHICS COMMITEE (BREC)			
Address 1 WESTVILLA CAMPUS		Address 2 GOVAN MBEKI BUILDING	
City DURBAN	State/Province/Region JOHANNESBURG	Country SOUTH AFRICA	ZIP or Postal Code 4000

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

NONE

CONTINUATION PAGE - for Item 6

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

A5324 - A Randomized, Double-Blinded, Placebo-Controlled Trial Comparing Antiretroviral Intensification with Maraviroc and Dolutegravir with No Intensification or Intensification with Dolutegravir Alone for the Treatment of Cognitive Impairment in HIV

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. *(Select **one** of the following.)*

☐ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

☑ For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE *(mm/dd/yyyy)*	11. SIGNATURE OF INVESTIGATOR
02-Jul-2019	

(**WARNING**: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

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Sponsored by:
The National Institute of Allergy and Infectious Diseases

Industry Support Provided by:
ViiV Healthcare Ltd.

IND# 126,854

The ACTG Neurology Collaborative Science Group:

Chair:	**Bandile Smith, MD,**
Chair Co-Chair:	**Lesedi Smit, MD**
Vice-Chair:	**Amahle Williams, MD**
DAIDS Clinical Representative:	**Prince Louw, MD Clinical**
Trials Specialist:	**Junior Marais, MD**

Final Version 2.0
April 25, 2019

A Randomized, Double-Blinded, Placebo-Controlled Trial Comparing Antiretroviral Intensification with Maraviroc and Dolutegravir with No Intensification or Intensification with Dolutegravir Alone for the Treatment of Cognitive Impairment in HIV

SIGNATURE PAGE

I will conduct the study in accordance with the provisions of this protocol and all applicable protocol-related documents. I agree to conduct this study in compliance with United States (US) Health and Human Service regulations (45 CFR 46); applicable U.S. Food and Drug Administration regulations; standards of the International Conference on Harmonization Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee determinations; all applicable in-country, state, and local laws and regulations; and other applicable requirements (e.g., US National Institutes of Health, Division of AIDS) and institutional policies.

Principal Investigator: BANDILE SMITH
Print/Type

Signed: _____ **Date:** _____
Name/Title

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TITLE: HVTN 705NAC89220HPX2008: A multicenter, randomized, double blind, placebo-controlled phase 2b efficacy study of a heterologous prime/boost vaccine regimen of Ad26.Mos4.HIV and aluminum phosphate-phosphate=adjuvanted Clade C gp140 in preventing HIV-1 infection in women in sub-Saharan Africa. Degree: Non-degree
BREC REF NO:
BFC251/17

The Biomedical Research Ethics Committee (BREC) has considered the abovementioned application at a meeting held on 09 May 2017.

This approval is valid for one year from 31 Jun 2019. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethlcs/Biomedical-Research·Ethics.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

Biomedical Research
Ethics Committee
Professor J Tsoka-
Gwegweni (Chair)
Westville Campus,
Govan Mbeki Building
Postal Address:
Private Bag X54001,
Durban 4000
Telephone: +27 (0) 31 260 2486 Facsimile: +27 (0) 31 260 4609 Email: brec@ukzn.ac.za

The following Committee members were present at the meeting that took place on 09 May 2019:

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

PROFESSOR v RAMBIRITCH
Deputy Chair: Biomedical Research Ethics Committee

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Professor Virendra Rambiritch	Chair (Pharmacology)
Professor Douglas Wassenaar	Deputy Chair - Clinical Psychologist
Dr Colleen Aldous	Genetics
Dr Nathlee Abbai	Microbiology and Molecular Biology
Prof Rajendra Bhimma	Pediatrics & Child
Health Rev Siziwe D Chili	Lay member
Dr Shayhana Ganesh	Research clinician
Dr Rohen Harrichandparsad	Neurosurgery
Dr Timothy Hardcastle	Surgery – Trauma
Dr Khumbulani Hlongwana	Public Health
Mr Hilton Humphries	Research Psychology and Public Health
Dr Bavna Hira	Obstetrics
Dr Zakhele Khumalo	General Medicine
Dr. Munira Khan	HIV Clinician
Dr Richard Lessells	Senior Infectious Diseases Specialist
Dr Keshena Naidoo	Family Medicine
Dr Saeeda Paruk	Psychiatry
Dr Takshita Sookan	Biokinetics, Exercise and Leisure Sciences
Prof Ann Strode	Health Law
Dr. KT MNGADI	Caprisa

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PERSONAL DETAILS/SITE DETAILS			
Name as per SA ID:	Dr. KT MNGADI	**Telephone No:**	(031) 66676262
Designation:	PRINCIPAL INVESTIGATOR	**Cellphone No:**	872828278
Site/Institution name:	CAPRISA	**Fax No:**	(031)
Postal Address:	ETHEKWINI CRS, 3 RICHARDS ROAD, BEREA, JOHANNESBURG, SOUTH AFRICA, 4001	**E-Mail:**	Kathy.mngadi@caprisa.org
Physical Address:	ETHEKWINI CRS, 3 RICHARDS ROAD, BEREA, JOHANNESBURG, SOUTH AFRICA, 4001	**HPCSA/SANC/SAPC NO:**	
Current personal medical malpractice			

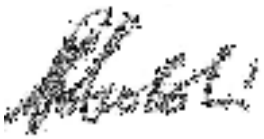
ACADEMIC QUALIFICATIONS		
Qualification	**Institution**	**Year**
MD	CAPRISA	2001
MBBS	CAPRISA	1996

Training	**Course Provider**	**Date of Course**
Face to Face GCP Course	**PPD**	**01-Jun-2018**
Online GCP	PPD	**01-Jun-2016**
Online HSP	PPD	**01-Jun-2019**
Other relevant		

RELEVANT RELATED WORK EXPERIENCE AND CURRENT POSITION		
Period	**Position**	**Employer**

Peer-reviewed publications in the past 3 years:

Any additional relevant information supporting abilities to participate in conducting this trial [briefly]:



Signature:

02-Jul-2019

Date:

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Screening Date	Participant Name	Participant ID Number	PTID	Enrollment Date (enter NONE if not enrolled	Date Discontinued or Screened out of Study	Reason for Screening Failure or Discontinuation from Study	Recruitment Strategy
02-Jul-2019	Robert Williams	1212	1001	10-Jul-2019			Reference
03-Jul-2019	Ray Smith	1342	1002	NONE			Reference
03-Jul-2019	Hanse Odal	1564	1003	11-Jul-2019			Advertisements
04-Jul-2019	Jamal Singh	1872	1004	13-Jul-2019			Reference
04-Jul-2019	Adele Smith	1652	1005	15-Jul-2019			Advertisements
08-Jul-2019	Ray Philips	1762	1006	NONE			

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Site Visit Information

Clinical Research Site (CRS) Number:	101	**Visit Date(s):**	
CRS Name: **Modality: Onsite**	Onsite	**CRS Address, City, State, Country:**	Caprisa, South Africa

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Institution Number: 1245	**Manufacturer:**	
Investigator Name: Dr. KT MHAGDI	**Dosage Form and Strength: Tablet and 100 mg**	
Protocol No.:	**Lot No.: NA**	**Expiry Date: NA**
Protocol Title: A Randomized, Double-Blinded, Placebo-Controlled Trial Comparing Antiretroviral Intensification with Maraviroc and Dolutegravir with No Intensification or Intensification with Dolutegravir Alone for the Treatment of Cognitive Impairment in HIV	**Storage Location:** **Cabinet in PIs room**	**Storage Temp. :** 24 to 32 degrees Celsius

Line No.	Date	Dispensed To / Received From	Lot Nos with quantities	Balance	Recorder's Initials/Sign
Ex.	*15Feb2012*	*Manufacturer*	*12 - +100 tabs*	*100*	*JAD*
1.	08-Aug-19	ABC Pharma	128 - +100 tabs	20	DAS
2.	18-Aug-19	ABC Pharma	129 - +100 tabs	10	DAS
3.	23-Aug-19	ABC Pharma	130 - +100 tabs	5	DAS
4.	30-Aug-19	ABC Pharma	131 - +100 tabs	8	DAS
5.	01-Sep-19	ABC Pharma	132 - +100 tabs	7	DAS
6.	08-Sep-19	ABC Pharma	133 - +100 tabs	4	DAS
7.	18-Sep-19	ABC Pharma	134 - +100 tabs	10	DAS
8.					
9.					
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(Shaded boxes indicate participant is *not eligible* for HVTN 702)

Allergies				**No**	**Yes**
Have you ever had an allergic reaction to a vaccine, medication, food (eggs), or any other substance? If **yes**, complete table for each allergen:					
Allergen:					
Date of last reaction:	☐ unknown	☐ unknown	☐ unknown		
Treatment: (Y/N)					
Type of reaction: (check all that apply)	☐ Hives or rash ☐ Itchy skin ☐ Watery/itchy eyes ☐ Sneezing or nasal congestion ☐ Chest tightness ☐ Difficulty breathing ☐ Abdominal pain ☐ Angioedema: (swelling of the tongue, mouth or face) ☐ Anaphylaxis ☐ Don't know	☐ Hives or rash ☐ Itchy skin ☐ Watery/itchy eyes ☐ Sneezing or nasal congestion ☐ Chest tightness ☐ Difficulty breathing ☐ Abdominal pain ☐ Angioedema: (swelling of the tongue, mouth or face) ☐ Anaphylaxis ☐ Don't know	☐ Hives or rash ☐ Itchy skin ☐ Watery/itchy eyes ☐ Sneezing or nasal congestion ☐ Chest tightness ☐ Difficulty breathing ☐ Abdominal pain ☐ Angioedema: (swelling of the tongue, mouth or face) ☐ Anaphylaxis ☐ Don't know		
Have you ever had any unexplained angioedema (swelling of the tongue, mouth or face)?					(shaded)
• If history of allergy, check exclusion criteria specifics					
Comments:					n/a ☐

Autoimmune Disorders - Have you ever been told by a doctor that you had an…	**No**	**Yes**
autoimmune disease? (Hashimoto's Thyroiditis, Pernicious Anemia, Addison's Disease, Rheumatoid Arthritis, Lupus, Multiple Sclerosis, Myasthenia Gravis, Grave's Disease, Celiac Disease, Sprue, Psoriasis, Sarcoidosis, Scleroderma, Diabetes Mellitus) [If Yes, circle applicable]		(shaded)
Comments:		n/a ☐

Cardiovascular Conditions - Do you or have you ever had problems with	**No**	**Yes**
coronary artery disease/ heart attack/ angina/ stroke/ transient ischemic attack? [if yes, circle applicable]		
chest pain / shortness of breath with mild activity? [if yes, circle applicable]		
enlarged heart/ congestive heart failure? [if yes, circle applicable]		
heart valves such /infection of the heart/abnormal heart beat), palpitations? [if yes, circle applicable]		
cardiac arrhythmias?		
Comments:		n/a ☐

Cardiac Risk	**No**	**Yes**
Do you have hypertension (high blood pressure)? [If yes, ask about medication]		
Do you smoke cigarettes?		
Did you ever have high fat/cholesterol in the blood? [If yes, ask about medication]		
Comments:		n/a ☐

Pulmonary Conditions - Do you or have you ever had…	**No**	**Yes**
Tuberculosis		
Emphysema or COPD? [if yes, circle applicable]		
Asthma or wheezing? [if yes, circle applicable]		
If yes to asthma: - Do you use a bronchodilator daily?		
- Have you had >1 exacerbation of symptoms treated with oral steroids in the 30 days?		
- Have you routinely used moderate to high dose inhaled corticosteroids or theophylline in the last year?		
- Did you need emergency care, urgent care, hospitalization, or intubation for asthma in the last year?		
Comments:		n/a ☐
Gastrointestinal Conditions - Do you or have you ever had…	**No**	**Yes**
Vomiting blood/bloody stools		
Liver infection [ask about medication]		
any other gastrointestinal problems: [specify]		
Comments:		n/a ☐
Endocrine Conditions - Do you or have you ever had…	**No**	**Yes**
Diabetes Type 1 or 2 (not including problems with blood sugar while pregnant)?		
a thyroidectomy (surgical removal of the thyroid) or Thyroid disease? [ask about medication]		
any other endocrine or hormone problems?[specify]		
Comments:		n/a ☐
Neurologic Conditions - Do you or have you ever had…	**No**	**Yes**
any seizures? [ask about medication]		
other neurological conditions?[specify]		
Comments:		n/a ☐
Other Medical Conditions - Do you have or have you ever had…	**No**	**Yes**
a *chronic* kidney disease?[specify]		
an immunodeficiency disease (difficulty fighting infections, frequent infections)?[specify]		
a bleeding disorder (excessive bleeding or bleeding that happens without injury)?[specify]		
anemia (low red blood cell count)? [ask about medication]		
cancer?[specify]		
Comments:		n/a ☐
Mental Health History - Have you ever…	**No**	**Yes**
sought guidance from a therapist or psychiatrist for any reason?		
experienced a period of anxiety and/or depression? [ask about medication] If yes, how long did you feel this way?		
heard voices or seen things that weren't really there? • INELGIBLE if patient experienced psychoses within the past 3 years		
had *feelings or thoughts* of hurting or killing yourself in the past 3 years ? • INELGIBLE if patient attempted suicide within the past 3 years; or has ongoing risk for suicide		
been to a hospital for mental health reasons?		
had any other mental health diagnoses? If yes, what?		
Comments:		n/a ☐

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Demographics Date of visit: _1_ _5_/_06_ __/ 2019__ __ Gender: ☐Female ☐Male Race: _____Asian_____ Date of birth: __ __/__ __ __/ __ __ Age: _____ Documentation of HIV? ☐Yes ☐No If yes, date of HIV positive test: _____ If no, was HIV testing performed? ☐Yes ☐No Informed consent obtained □Yes □No Informed Consent Version No. _____ Version date __ __/__ __ __ /__ __ __ __	**1**	**2**	**3**	
				Informed consent
				HIV Rapid Test
				Screening Checklist
				Blood For confirmatory VL
				Vital Signs
				History of ART
				Past Medical History (including AIDS defining conditions)
				Signs and symptoms
				Physical exam
				Medication History
				Pregnancy test
				Nadir CD4 testing
				TB Screening
				Laboratory testing (hepatitis, metabolic panel, VL)
				2nd Level QC Staff Initials__ __ __ **Date**__ __/__ __ __/ __ __
				3rd Level QC Staff Initials__ __ __ **Date**__ __/__ __ __/ __ __

CONFIRMATION OF HIV TEST

Was Rapid HIV testing done? ☐Yes ☐No

Results? ☐Positive ☐Negative

SCREENIG CHECKLIST

Was Screening checklist filled in? ☐Yes ☐No

Was screening number obtained? ☐Yes ☐No

Specify Number_____

INITIAL VIRAL LOAD

Was blood for initial Viral load collected? ☐Yes ☐No

Do you recall any CD4 lower than that recorded in your referral form ☐Yes ☐No

Do you recall when you were first diagnosed with HIV? ☐Yes ☐No

If yes SPECIFY

What do you think predisposed you to HIV infection?

- ☐ Homosexual relationship
- ☐ Heterosexual relationship
- ☐ Intravenous drug use
- ☐ Blood transfusion
- ☐ Occupational exposure
- ☐ Does not want to answer

Others

Date__ __/__ __ __ /__ __ __ __ **Time**_____Hrs **Initials**_____