Microbicide R&D to **A**dvance HIV Prevention **T**echnologies through **R**esponsive **I**nnovation and e**X**cellence (MATRIX)

Clinical Research Site (CRS) Capacity Catalogue:

Baseline Assessment

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MATRIX
Advancing R&D of Innovative HIV Prevention Products for Women

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LIST OF ACRONYMS

A/CASI	audio / computer-assisted survey instrument
AGYW	adolescent girls and young women
ARV	antiretroviral
BACH	Business, mArket dynamics and Commercialization Hub
CAB	Community Advisory Board
CAPRISA	Centre For the Aids Programme of Research in South Africa
CaSE	Capacity Strengthening, Engagement and mentorship
CONRAD	Contraception Research and Development
CRS	clinical research site
CVF	cervicovaginal fluid
D2D	Design to Delivery
DBS	dried blood spot
EVG	elvitegravir
FGD	focus group discussion
FIH	first-in-human
FSW	female sex workers
HHRC	Harare Health and Research Consortium
IDI	in-depth interview
IEC	independent ethics committee
IRB	institutional review board
IVR	intravaginal ring
KEMRI	Kenya Medical Research Institute
MATRIX	Microbicide R&D to Advance HIV Prevention Technologies through Responsive Innovation and eXcellence
MPT	multi-purpose technology
PBFW	pregnant and/or breastfeeding women
PK	pharmacokinetic
R&D	research and development
SBR	social and behavioral research
SMS	short messaging service
SOP	standard operating procedures
SRH	sexual and reproductive health
SSA	sub-Saharan Africa
TAF	tenofovir alafenamide
Wits RHI	Wits Reproductive Health and HIV Institute

OVERVIEW AND RATIONALE

The mission of the MATRIX (Microbicide R&D to Advance HIV Prevention Technologies through Responsive Innovation and eXcellence) Collaborative is to develop a range of feasible, acceptable, affordable, scalable and deliverable products to meet the diverse HIV prevention needs of women and girls in sub-Saharan Africa (SSA), a key population disproportionately impacted by the HIV/AIDS epidemic. Furthermore, a major guiding principle of MATRIX is that all activities are grounded in North-South partnerships to enhance research and development (R&D) capacity in SSA for sustainability in the region. The project is designed to: positively accelerate early R&D for new HIV prevention products by providing an innovative ecosystem in which these early-stage technologies can be advanced; and support equitable collaboration among institutions, scientists, implementers, industry partners, and other stakeholders worldwide to achieve shared priorities, with an emphasis on providing opportunities for the participation and leadership of local partners in the countries where these new products are most needed. While MATRIX is focused on expanding HIV prevention options for all women and girls in SSA, non-vaginally administered HIV prevention technologies developed through the program would also expand HIV prevention options for all other key populations disproportionately impacted by the epidemic.

MATRIX partners have deep inter-disciplinary product R&D-related experience in women-initiated HIV prevention methods, including expertise in the following: developing a range of antiretroviral (ARV)-based prevention modalities; drug formulation and delivery; long-acting, topical and systemic drug delivery; sexual and reproductive health (SRH); HIV prevention product development; social and behavioral research (SBR); market strategy and business case assessments; and capacity strengthening. MATRIX is currently partnered with four Product Developers working on six novel products at various stages of development: Contraception Research and Development's (CONRAD) tenofovir alafenamide/elvitegravir (TAF/EVG) insert, cabotegravir hydrogel depot and cabotegravir pellet implant; Population Council's Griffithsin fast-dissolving insert; Oak Crest Institute's non-ARV non-hormonal multipurpose technology (MPT) intravaginal ring (VR); and the University of Pittsburgh's extended-release vaginal film. MATRIX will provide fiscal and administrative oversight through the Prime, and additional support to Product Developers' R&D efforts through five cross-cutting Activity Hubs: Technology Accelerator, Design to Delivery (D2D), Business, MArket Dynamics and Commercialization Hub (BACH), Capacity Strengthening, Engagement and Mentorship (CaSE), and Clinical Trials. MATRIX is currently partnered with five clinical research sites (CRS) in SSA: Aurum Institute, Centre For the Aids Programme of Research in South Africa (CAPRISA), Harare Health and Research Consortium (HHRC), Kenya Medical Research Institute (KEMRI), and Wits Reproductive Health and HIV Institute (Wits RHI).

MATRIX partners will actively include women and girls from South Africa, Zimbabwe, and Kenya in all aspects of pre-clinical and clinical research, providing multiple mechanisms for their unique perspectives, contexts and experiences to inform the direction of product development so that our HIV prevention products meet their varied needs. However, given the ethical and scientific requisites of first-in-human (FIH), pharmacokinetic (PK) and other early-stage clinical studies of new HIV prevention products, planned clinical trials will mostly enroll healthy, adult women at relatively low risk of acquiring HIV. MATRIX CRS partners must be able to not only engage and

recruit our target study populations from the communities they serve, but also to conduct the requisite procedures and assessments necessary for early-stage clinical research. To that end, the five current MATRIX CRS partners – Aurum, CAPRISA, HHRC, KEMRI, and Wits RHI – completed a baseline assessment to document their core capacities.

The baseline CRS Capacity Questionnaire was distributed to our CRS partners to assess their presumptive eligibility to participate in planned clinical research protocols (active product and/or placebo). Presumptive eligibility criteria include training and experience of the lead investigator(s) at the site(s), potential access to the designated study population(s), previous experience in conducting early stage and placebo studies, laboratory capacity, pharmacy capacity, sample storage and shipment capacity, infrastructure for regulatory compliance and oversight, and community engagement capacity. Upon receipt and review of a protocol concept from the Product Developers, MATRIX leadership will utilize the information collected through the baseline CRS Capacity Questionnaire to determine which CRS partners to solicit for an application to participate in the study. Presumptively eligible CRS partners will then complete study-specific CRS Capacity Questionnaires listing the specific site requirements and qualifications considered necessary for successful study implementation. Selection of CRS partners to participate in a study will be based on information previously provided for the baseline CRS Capacity Questionnaire and their written responses to the study-specific CRS Capacity Questionnaire.

Site responses to the baseline CRS Capacity Questionnaire were collected and are hereby summarized in this MATRIX CRS Capacity Catalogue document. The CRS Capacity Catalogue is meant to inform decisions about our CRS partners' presumptive eligibility for upcoming clinical research protocols. This document will be updated annually to incorporate site responses to study-specific CRS Capacity Questionnaires completed as part of the site selection process for clinical research protocols.

SUMMARY OF SITE RESPONSES TO CRS CAPACITY QUESTIONNAIRES

The following sub-sections provide aggregated summaries of site responses to key CRS capacity questions in the baseline CRS Capacity Questionnaire. The summaries below will be updated annually with information gathered as part of the site selection process for our clinical research protocols.

Clinical trial and investigator-driven experience

All five current CRS partners have prior experience recruiting and enrolling healthy, HIV-uninfected women between the ages of 18-45 years for clinical research studies, and all have recent experience conducting clinical trials of investigational HIV prevention products. Three CRS partners have prior experience conducting FIH/Phase 1 clinical trials and four CRS have experience conducting PK studies. Two CRS partners have prior experience conducting placebo clinical studies and/or investigational contraceptive product clinical studies.

All five CRS partners have established relationships in their communities to access additional target study populations for non-clinical research: adolescent girls and young women (AGYW) between the ages of 16-17 years, pregnant and/or breastfeeding women (PBFW), and female sex workers (FSW). All five CRS partners have prior experience conducting SBR studies using qualitative methods (in-depth interviews [IDI] and/or focus group discussions [FGD]) and computer-based data collection tools (short messaging service [SMS] and/or audio / computer-assisted survey instruments [A/CASI]).

Clinical, laboratory and pharmacy capacity

All five CRS partners are currently able to perform all clinical data collection activities and procedures likely needed for our planned clinical trials on-site, except cervical tissue biopsies; three CRS are currently able to perform cervical tissue biopsies. All five CRS partners are currently able to process and store all laboratory specimens on-site, except Pap smears and cervicovaginal fluid (CVF). Four CRS are currently able to process/store CVF and three are currently able to process/store Pap smears.

All five CRS partners are currently able to perform all laboratory specimen testing on-site or at their institution's central lab, except blood safety panels (all CRS send off-site for testing), microscopy (one CRS sends off-site for testing) and Pap smear (one CRS sends off-site for testing). All five CRS partners have standard operating procedures (SOP) and/or systems to track laboratory specimens, and all are currently able to store and ship specimens under cold-chain conditions.

Four CRS partners are currently able to accommodate extended clinic visits if needed, with three currently able to accommodate overnight stays. All five CRS partners have full-time pharmacists on-site, secure and restricted-access spaces for product storage and dispensing, biosafety cabinets, backup power supply, and continuous temperature monitoring systems; four CRS have clean rooms for product preparation. All five CRS partners have SOPs and/or systems for product storage, product accountability management, and product destruction.

Regulatory experience and capacity

All five CRS partners require both parental consent and minor participant assent to include minors (<18 years old) in research. Institutional review boards (IRB) and independent ethics committees (IEC) at all CRS meet once a month to review materials submitted for approval. The timeframe to achieve all necessary regulatory approvals for clinical research ranges from three to eight months depending on the country. Specimen shipment permits can likewise take months to receive, with permit renewal requirements varying by country.

Community engagement capacity

All five CRS partners have at least one community advisory board (CAB) that meets every 1-2 months. All CRS have plans/SOPs to engage potential trial participants pre-, during and post-

study, and to address barriers to clinic visit attendance by participants (e.g., transport, flexible clinic hours, outreach, etc.).

CRS CAPACITY CATALOGUE

The following section provides a detailed table summarizing individual sites' responses to all CRS capacity questions in the baseline CRS Capacity Questionnaire. The table will be updated annually with information gathered as part of the site selection process for our clinical research protocols.

Table 1 below describes core capacities of the three MATRIX CRS partners located in South Africa – Aurum, CAPRISA and Wits RHI – and the single MATRIX CRS partners located in Zimbabwe and Kenya – HHRC and KEMRI, respectively. Aurum, CAPRISA and KEMRI provided information for more than one site/location when completing their baseline CRS Capacity Questionnaire. For these three CRS, the information presented herein refers to their main site/location – Klerksdorp for Aurum, eThekwini for CAPRISA, Thika for KEMRI – unless otherwise specified. Acronyms not previously used in this document are defined at the end.

Table 1: **CRS Capacity Questionnaire results, by site**

Core CRS Capacities	South Africa			Zimbabwe	Kenya
	Aurum	**CAPRISA**	**Wits RHI**	**HHRC**	**KEMRI**
Lead Investigator qualifications	MBChB; 11 yrs as Lead Investigator at CRS	PhD; 12 yrs as Senior Scientist & 2 yrs as Head of QA at CRS	PhD, MSc; 11 yrs as Clinical Trials and Lab Director at CRS	MBChB, MMed; 13 yrs as Lead Investigator at CRS	MBChB, MMed, MPH; 5 yrs as Chief Research Officer at CRS PhD, MSc; 6 yrs as Community Health Dept. Chair & 4 yrs as Assoc. Professor at JKUAT
Additional study leadership – Clinicians	3 (Klerksdorp) 1 (Pretoria) 1 (Rustenburg) 1 (Tembisa #2) 4 (Tembisa #4)	1 (eThekwini) 4 (Vulindlela)	3	1	3
Additional study leadership – Coordinators	1	2 (eThekwini) 1 (Vulindlela)	3	2	1
Access to study populations – Healthy, HIV-uninfected adult women	√ Also has experience recruiting	√ Also has experience recruiting	√ Also has experience recruiting	√ Also has experience recruiting	√ Also has experience recruiting

Core CRS Capacities	South Africa			Zimbabwe	Kenya
	Aurum	**CAPRISA**	**Wits RHI**	**HHRC**	**KEMRI**
Access to study populations – AGYW	√ Also has experience recruiting (Rustenburg only)	√	√ Also has experience recruiting	√ Also has experience recruiting for SBR	√ Also has experience recruiting
Access to study populations – PBFW	√	√	√ Also has experience recruiting for SBR	√ Also has experience recruiting	√ Also has experience recruiting
Access to study populations – FSW	√	√	√	√	√
Administrative – Essential documents storage	√	√	√	√	√
Administrative – Direct data entry & management	√ Nukleus, REDCap, InForm, MediData Rave	√ REDCap, MediData Rave	√ REDCap, InForm, Survey Solutions, MediData Rave	√	√
Administrative – Risk mitigation procedures &/or disaster management plans	√ COVID-19 Management & Power Failure and Natural Disasters SOPs submitted	√ Emergency Procedures, Risk Assessment & Fire Protection SOPs + Disaster Management and Evacuation Plans submitted	√ COVID-19 Response SOP submitted	√ Disaster Preparedness SOP submitted	No plans/SOPs submitted
Clinical Trial and Investigator-Driven Research Experience					
IND/IDE trials of HIV prevention products/drugs	√	√	√	√	√
FIH/Phase 1 safety and acceptability studies	√	√	√		
PK studies	√ (Pretoria & Tembisa #2 only)	√	√		√
Placebo clinical studies			√	√	

Core CRS Capacities	South Africa			Zimbabwe	Kenya
	Aurum	**CAPRISA**	**Wits RHI**	**HHRC**	**KEMRI**
IND/IDE trials of contraceptive products/drugs	√				√
SBR incorporating qualitative methodologies	√ IDI, FGD	√ IDI, FGD	√ IDI, FGD	√ IDI, DCE	√ IDI, FGD
SBR incorporating electronic data collection tools	√ A/CASI	√ A/CASI	√ SMS, A/CASI	√ A/CASI	√ SMS
Clinical Capacity					
Facilities – # of clinical rooms	18 (Klerksdorp) 3 (Pretoria) 12 (Rustenburg) 18 (Tembisa #2 & 4)	13 (eThekwini) 12 (Vulindlela)	10	5	15 (Thika) 12 (Nairobi)
Facilities – # of waiting areas	5 (Klerksdorp) 2 (Pretoria) 4 (Rustenburg) 6 (Tembisa #2 & 4)	2 (eThekwini) 2 (Vulindlela)	4	2	1 central reception area
Facilities – # of counseling rooms	8 (Klerksdorp) 12 (Rustenburg) 5 (Tembisa #2 & 4)	4 (eThekwini) 3 (Vulindlela)	7	2	5
Facilities – Dedicated space for SBR activities	√ A/CASI, IDI, FGD	√ A/CASI, IDI, FGD	√ A/CASI, IDI, FGD	√ A/CASI, IDI	√ IDI, FGD
Facilities – Dedicated space for data management	√ (All locations)	√ (All locations)	√ Data center w paper and electronic systems	√ 2 rooms for data entry, storage, transmission	√ 3 data rooms w secure archives
Extended clinic visits possible	√ Includes overnight stay (Pretoria only)	√ Includes overnight stay	√ Includes overnight stay	√	√ Includes overnight stay
On-site systemic counseling	√	√	√	√	√
On-site phlebotomy	√	√	√	√	√
On-site rapid HIV testing	√	√	√	√	√

Core CRS Capacities	South Africa			Zimbabwe	Kenya
	Aurum	CAPRISA	Wits RHI	HHRC	KEMRI
On-site confirmatory HIV testing	√ (Central lab)	√ (Central lab)	√	√ (Central lab)	√ (Central lab)
On-site STI testing using NAAT		√ GeneXpert; CT/NG; Additional tests at central lab	√ GeneXpert; CT/NG/Trich	√ GeneXpert; CT/NG/Trich (Central lab)	√ (Central lab)
On-site rapid pregnancy testing	√	√	√	√	√
On-site physical exam	√	√	√	√	√
On-site pelvic exam	√	√	√	√	√
On-site CVF & CVL collection	√	√	√	√	√
On-site cervical tissue biopsy collection		√		√	√
Laboratory Capacity					
Personnel training	IATA & GCLP certification every 2 yrs	IATA & GCLP certification every 2 yrs	IATA & GCLP certification every 2 yrs	IATA & GCLP certification every 2 yrs	IATA & GCLP certification every 2 yrs
Lab facilities	On-site labs + central lab	On-site labs + central lab	On-site lab	On-site lab + central lab	On-site lab + central lab
Lab specimens – whole blood, serum, and plasma	√	√	√	√	√
Lab specimens – DBS	√	√	√	√	√
Lab specimens – urine	√	√	√	√	√
Lab specimens – CVF/CVL	√	√	√	√	
Lab specimens – Pap smear	√			√	√
Lab specimens – cervical tissue biopsies		√		√	√
Lab specimens – microscopy	√	√	√	√	√

Core CRS Capacities	South Africa			Zimbabwe	Kenya
	Aurum	**CAPRISA**	**Wits RHI**	**HHRC**	**KEMRI**
Lab specimens – other	PBMC, sputum	PMBC, cytobrushes	Specimen slides, genital & endocervical swabs, menstrual cup samples	Hair, vaginal & endocervical swabs, sputum & saliva, MTB isolates, PBMC	Mucosal samples, hair, swabs, PBMC
Off-site/outsourced lab testing	Hematology, blood chemistries, safety blood tests Tests conducted at central or off-site labs	Pap smear, hematology, blood chemistries, safety blood tests	Pap smear, hematology, blood chemistries, safety blood tests	Hematology, blood chemistries, safety blood tests, microscopy Tests conducted at central or off-site labs	Likely able to conduct all tests at on-site or central lab
Off-site labs typically used	BARC SA, CLS, NICD, Cytespace Africa	BARC SA	BARC SA, CLS, NHLS, NICD; All within 10km of site	BARC SA, CLS, NICD, UCT	Diagnostic and Medicolegal, University of Washington Mombasa Women's, KEMRI-RCTP, KEMRI-CGHR, UNITID, Metropolis, KAVI
Specimen tracking method(s)	SOPs; Chain of custody logs/forms; LDMS & Prelink System	Requisition forms; Shipping manifests; Chain of custody forms	SOPs; Chain of custody logs/forms; LDMS	SOPs; Chain of custody logs/forms; LDMS	SOPs; Chain of custody logs/forms; Freezerworks
Sample transport logistics (e.g., distance/time to lab)	Courier to central or off-site labs	Real-time courier to central lab located 10 min from site	On-site lab is on same floor as clinical rooms	Regularly scheduled courier to central lab located 30km (40 min) from site	Dedicated, same day courier to central lab located 40 km (45 min) from site
Cold chain storage and/or shipment	2 -80°C & 2 -20°C freezers; Cold pack/dry ice/liquid nitrogen packaging as needed for shipping to central or off-site labs	-80°C freezers; Coldpack/dry ice packaging as needed for shipping to central or off-site labs	6 -80°C & 2 -20°C freezers; Coldpack/dry ice & cryovial box packaging as needed for shipping to off-site labs	-80°C & -20°C freezers; Coldpack/dry ice/solid CO^2/dry nitrogen packaging as needed for shipping to central or off-site labs	5 -80°C & 2 -20°C freezers; Coldpack/dry ice packaging as needed for shipping to central or off-site labs
Pharmacy Capacity					
Available personnel	2 FT pharmacists; 1 locum pharmacist	5 FT pharmacists; 2 pharmacy technicians	2 FT pharmacists; 1 locum pharmacist	3 FT pharmacists; 1 pharmacy technician	1 FT pharmacist; 2 pharmaceutical technologists

Core CRS Capacities	South Africa			Zimbabwe	Kenya
	Aurum	**CAPRISA**	**Wits RHI**	**HHRC**	**KEMRI**
Restricted access & secure storage/dispensing space	√	√	√	√	√
Biosafety cabinet(s)	√ Class IIA2	√ Class IIA2, Class IIB2	√	√ Class IIB2	No response
Clean room(s)		√	√	√	No response
Continuous temperature monitoring system(s)	√ Omniflex; Auto-alerts	√ Omniflex; Auto-alerts	√ Immonit; Auto-alerts	√ Sensaphone; Auto-alerts	√ Testo saveris; Auto-alerts
Backup power supply	√ 1ry & 2ry generators	√ 1ry & 2ry generators	√ Generator	√ Generator; Solar inverter	√ Generator
System(s) for product storage & accountability management	SOPs; Accountability logs	SOPs; Accountability logs; Electronic dispensing program (iDART)	Accountability logs; Electronic dispensing program (Propharm)	SOPs; Accountability logs	SOPs; Accountability logs
System(s) for product destruction	SOPs; Off-site contractor; Destruction certificate	SOPs; Off-site contractor; Destruction certificate	SOPs; Destruction logs; Off-site contractor; Destruction certificate	SOPs; Destruction logs; Off-site contractor; Destruction certificate	SOPs; KPPB review/approval
Regulatory Experience and Capacity					
Age of research consent – General	18yo	18yo	18yo	18yo	18yo
Age of research consent – Married vs. unmarried	No difference	No difference	No difference	Married minors <18yo may be considered emancipated on case-by-case basis	No difference; Minors 15-17yo with children considered emancipated
Age of research consent – With vs. without children	No difference	No difference	No difference	Minors <18yo with children may be considered emancipated on case-by-case basis	Minors 15-17yo with children considered emancipated

Core CRS Capacities	South Africa			Zimbabwe	Kenya
	Aurum	CAPRISA	Wits RHI	HHRC	KEMRI
Parental consent & minor assent regulatory process(es)	Both parental consent & minor participant assent required	Both parental consent & minor participant assent required	Both parental consent & minor participant assent required	Both parental consent & minor participant assent required; Only minor consent required if emancipated	Both parental consent & minor participant assent required; Only minor consent required if emancipated
Specimen shipment regulatory process(es)	Wits BEC approval (all locations except Tembisa); MTA between site & receiving lab (Tembisa only); Export permit from SA DoH	MTA between site & receiving lab; Export permit from SA DoH; CDC import permit from receiving lab in US	MTA between site & receiving lab; Export permit from SA DoH; CDC import permit from US receiving lab in US	Specimen Transfer Agreement (STA) between site & receiving lab approved by RCZ	Export permits from KEMRI SERU & KPPB; CDC import permit, customs invoice & samples declaration needed to apply for KPPB export permit
Specimen shipment regulatory challenges	Up to 3-4 months for Wits BEC approval; Up to 3 months for SA DoH export permit	Major delays w SA DoH; Up to 8 months to get permits	≥3 months for SA DoH export permit	Permit valid for 1 year; New STA required for renewal; Permit only valid for testing specified in STA	KEMRI SERU export permit can take up to 4 months to process, is valid for 3 months, and can only be used for one shipment; KPPB export permit can take up to 4 weeks to process
Typical IRB/IEC approval timeline(s)	Parallel submissions Wits HREC: 2-3 months SAHPRA: 2-3 months; 1 month for import permit VAT exemption	Sequential submissions UKN BREC: 3 months SAHPRA: 2-3 months	Parallel submissions Wits HREC: 1-3 months SAHPRA: 1-3 months; 1 month for import permit VAT exemption	Parallel submissions after Chitungwiza HD, then RCZ last Chitungwiza HD: 4 wks UZ JREC: 4-6 wks MRCZ: 4-6 wks MCAZ: 8-12 wks RCZ: 4-6 wks	Sequential submissions KEMRI CCR: 4-6 wks KEMRI SERU: 4-8 wks KPPB: 8-12 wks NACOSTI: 1 month
Typical IRB/IEC meeting dates	Wits HREC: Last Friday of each month SAHPRA: Once a month	UKN BREC: Every 2nd Tuesday of month SAHPRA: Once a month	Wits HREC: Last Friday of each month SAHPRA: Once a month	UZ JREC: Rolling basis MRCZ: Last Thursday of every month	KEMRI CCR: Every 1st Wednesday of month KEMRI SERU: Once a month (3 committees)

Core CRS Capacities	South Africa			Zimbabwe	Kenya
	Aurum	CAPRISA	Wits RHI	HHRC	KEMRI
				MCAZ: Every 1st Wednesday of month RCZ: Last Thursday of every month	
Community Engagement Capacity					
Composition of CAB(s)	18-member CAB represents site catchment areas; Adolescent Youth CAB in development	20-member CAB represents various sectors of population in site catchment areas	3 long-established and active CABs: Youth, HIV Prevention, HIV Treatment	Institution-wide Adult & Youth CABs representative in terms of gender, geography, key populations, and professional disciplines	Institution-wide CAB & study-specific CABs represent diverse community interests
Community engagement process(es) – Prior to study	Identify & meet w opinion leaders and gatekeepers; Strengthen CAB capacities; Develop participant referral network	Present upcoming study to CAB & obtain feedback; Consult CAB and other stakeholders to ensure buy-in and effective communication about key study details and messages	Monthly info sharing meetings w CABs; Ongoing by email & telephone	Train CAB on protocol; Compile stakeholder directory; Conduct community mapping; Broad community sensitization w other research organizations	Meeting(s) to present upcoming study to CAB & obtain feedback on recruitment strategies and materials
Community engagement process(es) – During study	Provide study updates to CAB & obtain input on issues impacting the study; Tailor communications to meet stakeholder needs	Meetings w CAB every 2 months to provide study updates, share best practices, conduct training, and obtain feedback on recruitment strategies	Monthly info sharing meetings w CABs; Ongoing by email & telephone	Targeted community sensitization/education; Work w focal locals; Pre-screening activities	Meetings to obtain CAB input on community members' concerns, challenges, successes, priorities, etc.
Community engagement process(es) – After study	Results disseminated to site staff, CABs, study participants, SA DoH, civil society forums and other relevant stakeholders	Dissemination plan lists all stakeholders w whom to share results, including method and order of priority	Monthly info sharing meetings w CABs; Ongoing by email & telephone	Schedule results dissemination events w all stakeholders, including study participants	Study updates and outcomes will be disseminated to the community w CAB support

Core CRS Capacities	South Africa			Zimbabwe	Kenya
	Aurum	CAPRISA	Wits RHI	HHRC	KEMRI
Mitigation of barriers to study visit attendance	Transportation provided to participants if needed; Flexible clinic hours; Outreach	Transportation provided to participants if needed; Flexible clinic hours; Outreach	Transportation provided to participants if needed; Flexible clinic hours; Off-site or remote visits possible	Travel permission letter and/or transportation provided to participants if needed; Flexible clinic hours; Outreach	Transportation provided to participants if needed; Outreach; Incentives

BARC SA – Bio Analytical Research Corporation South Africa; BEC – Biobank Ethics Committee; CDC – Centers for Disease Control and Prevention (United States); CLS – Clinical Laboratory Services; CT/NG/Trich – Chlamydia trachomatis / Neisseria gonorrhoeae / Trichomonas vaginalis; CVL – cervicovaginal lavage; DCE – discrete choice experiment; FT – full-time; GCLP – Good Clinical Laboratory Practice; HD – Health Department; IATA – International Air Transport Association; IND/IDE – Investigational New Drug / Investigational Device Exemption; JKUAT – Jomo Kenyatta University of Agriculture and Technology; KAVI – Kenya Aids Vaccine; KEMRI CCR – KEMRI Centre for Clinical Research; KEMRI-CGHR – KEMRI Center for Global Health Research; KEMRI-RCTP – KEMRI Research Care and Training Program; KEMRI SERU – KEMRI Scientific Ethics Research Unit; KPPB – Kenya Pharmacy & Poisons Board; LDMS – Laboratory Data Management System; MBChB – Bachelor of Medicine and Bachelor of Surgery; MCAZ – Medicines Control Authority of Zimbabwe; MMed – Master of Medicine; MPH – Master of Public Health; MRCZ – Medical Research Council of Zimbabwe; MSc – Master of Science; MTA – Material Transfer Agreement; MTB – Mycobacterium tuberculosis; NAAT – nucleic acid amplification test; NACOSTI – National Commission for Science, Technology and Innovation; NHLS – National Health Laboratory Service; NICD – National Institute for Communicable Diseases; PBMC – peripheral blood mononuclear cells; PhD – Doctor of Philosophy; QA – quality assurance; RCZ – Research Council of Zimbabwe; SA DoH – South Africa Department of Health; SAHPRA – South African Health Products Regulatory Authority; STA – Specimen Transfer Agreement; STI – sexually transmitted infection; UCT – University of Cape Town; UKN BREC – University of Kwazulu-Natal Biomedical Research Ethics Committee; UNITID – University of Nairobi Institute of Tropical and Infectious Diseases; UZ JREC – University of Zimbabwe College of Health Sciences and Parirenyatwa Group of Hospitals Joint Research Ethics Committee; Wits HREC – University of the Witatersrand Human Research Ethics Committee