CLINICAL TRIAL SITE CAPACITY CATALOGUE

A project of the Microbicide Donors Committee

Quick Working Group

April 2008

ALLIANCE FOR
MICROBICIDE
DEVELOPMENT

Contents

Acknowledgements

First and foremost, we extend our sincere thanks to the staff at each of the field sites who contributed to this Catalogue. *The Alliance is proud to have catalyzed this project, but this document is really a result of the sites' efforts and would not have been possible without their collaboration.*

We also thank Family Health International, the HIV Vaccine Trials Network, International AIDS Vaccine Initiative, Partnership for AIDS Vaccine Evaluation, US Centers for Disease Control and Prevention, and Voxiva. The survey distributed to each of the sites included in the Catalogue *was informed by comparable projects conducted by these organizations, whose contributions were significant and are greatly appreciated.*

We also express boundless gratitude to Carolyn Plescia, who bore the total responsibility for implementing this project concept and is its sole author.

Finally, we wish to thank those who support the activities of the Quick Working Group and the Microbicide Donors Committee: the Bill and Melinda Gates Foundation and the US Agency for International Development.

Executive Summary

Site selection is critical to the success of HIV prevention trials. The choice of a site with adequate facilities, well-trained personnel, substantial community support, and an appropriate participant population can enhance recruitment and retention, minimize costs, and ensure data integrity. Informed site selection and assessing site capacity have been of increasing interest to the microbicide field over the past few years. At the most recent meeting of the Microbicide Donors Committee, participants requested a comprehensive list of potential sites for upcoming microbicide and pre-exposure prophylaxis (PrEP) trials. Their rationale was that such a catalogue would allow sponsors and developers to make more informed decisions about where to conduct a given trial based on an inventory of each site's potential participant population as well as clinical, laboratory, and staffing capacity. They also thought that such a catalogue could optimize efficient use of existing sites and minimize costly and possibly inappropriate development of new sites.

In response to this interest, the Alliance has developed this *Clinical Trial Site Capacity Catalogue* of recent, active, and potential microbicide and PrEP trial sites. The *Catalogue* has benefited from discussions at the two most recent meetings of the Quick Working Group, which has been supportive of the concept. The activity was guided by a commitment to: (1) avoidance of "wheel reinvention"; (2) speed and simplicity; (3) reticence about imposing excessive response burdens on already busy people; and (4) ease of maintenance. The understanding was that the survey results could readily inform more elaborate undertakings going forward, as those proved necessary, and that it might be expanded to encompass other prevention interventions if it proved useful to do so.

The Alliance developed and distributed a survey instrument that was informed by similar tools developed by Family Health International, the HIV Vaccine Trials Network, the International AIDS Vaccine Initiative, the Partnership for AIDS Vaccine Evaluation, the US Centers for Disease Control and Prevention, and Voxiva. This survey requested the following information from each site:

- General information: principal sources of funding, institutional collaborations, in-country research review process, and availability of facilities including clean water, electricity, back-up generators, email/internet access, dedicated research computers, and international phone lines;
- Human resources and technical requirements: dedicated research personnel, GCP training for clinical staff, import/export procedures for trial materials, and SOPs for management of test materials;
- Communications and community involvement: establishment of a communications plan, presence of a dedicated communications officer, and existence of a community advisory board or other community research support group;
- HIV prevalence and incidence: the results, method, and date of the most recent data collected;
- Potential participant population: age distribution, primary mode of HIV transmission, involvement in commercial sex work, willingness to participate in a clinical trial, and investigator's estimate of the number of participants who might be recruited for a microbicide or PrEP trial;
- Testing, treatment, and care capacity: availability on-site or by referral of primary health care services, HIV counseling and testing, HIV treatment/care, ARV therapy, STI testing and treatment, contraceptive counseling, contraceptive methods, urine pregnancy testing, pelvic exam, Pap smear, and colposcopy;

- Laboratory capacity: description of storage facilities, GLP-compliant procedures, and quality assurance and control programs as well as ability to conduct on-site HIV rapid testing, HIV RNA PCR, HIV serology, hematology assays, renal function tests, liver function tests, CD4+ testing, viral load testing, STI testing, urine pregnancy testing, and Hepatitis B assay;
- Completed, ongoing, and planned trials conducted at each site; and
- Critical modifications that could be made to strengthen the site for optimal implementation of clinical trials.

As of April 2008, the Alliance has contacted all sites that have recently conducted, are currently conducting, or plan to conduct a microbicide or PrEP trial(s). The *Catalogue* includes information only for those sites that chose to respond by completing the survey. The Alliance always welcomes new sites to be included in the *Catalogue*. If the reader is aware of a site that should be included, please contact the Alliance by email at info@microbicide.org, by phone at 301-587-9690 or by mail at:

Alliance for Microbicide Development
Attn: Clinical Trial Site Capacity Catalogue
8484 Georgia Avenue, Suite 940
Silver Spring, Maryland 20910 USA.

It is our hope that this *Catalogue* will be equally beneficial to the field staff that has contributed information about their sites. For them, the *Catalogue* will serve as a means of disseminating accurate and comprehensive information about the facilities available at their site and the capacity to conduct future trials.

In sum, the purpose of this exercise was to serve different needs and populations across the microbicide field and to do so in a way that would be not too burdensome and would lend itself to expansion and regular updating as the work of the field goes forward. We look forward to comments that might make the next round of the *Clinical Trial Site Capacity Catalogue* even more useful.

List of Sites

Abbreviation	Site	Location
ARCA	AIDS Research Consortium of Atlanta	Atlanta, USA
BLHC	Bronx-Lebanon Hospital Center	New York, USA
BPCRS	Be Part Community Research Solutions	Paarl, South Africa
CAPRISA	Centre for the AIDS Programme of Research in South Africa	Durban, South Africa
CIDRZ	Centre for Infectious Disease Research in Zambia-Kamwala Study Clinic	Lusaka, Zambia
DTHF	Desmond Tutu HIV Foundation, Masiphumelele Clinic	Cape Town, South Africa
EC	Empilisweni Centre	Cape Town, South Africa
FEE	Fudación Ecuatoriana Equidad – Centro de Investigaciones Medicas	Guayaquil, Ecuador
ICRH	International Centre of Reproductive Health	Mombasa, Kenya
INMENSA	Investigaciones Medicas en Salud	Lima, Peru
ISIP	Isipingo Clinic	Durban, South Africa
IST	Dispensaire IST and Clinique Waly Diop	Cotonou, Bénin
KCMC	Kilimanjaro Christian Medical Centre	Moshi, Tanzania
KEMRI	Research Care and Treatment Program, Kenya Medical Research Institute	Kisumu, Kenya
LSHM	Laboratoire de Santé Hygiène Mobile	Yaoundé, Cameroon
MCR	Madibeng Centre for Research	Brits, South Africa
MDP MAW	MDP Mwanza, NIMR/AMREF/LSHTM Collaborative Projects	Mwanza, Tanzania
MIRIAM	Miriam Hospital/Brown University	Providence, USA
MRC DUR	HIV Prevention Research Unit/Medical Research Council: Durban	Overport, Durban, South Africa
MRC HLA	Medical Research Council: Hlabisa Clinic	Hlabisa, South Africa
MUDHOL	Mudhol and Jamkhandi – Arunodaya HIV Care and Support Centers	Mudhol, India
MUMS	Makerere University Medical School	Kampala, Uganda
NARI	Jehangir Hospital-NARI Clinic	Pune, India
PHIVA	PHIVA Project	Durban, South Africa
PU	Project Ubuzima	Kigali, Rwanda
QECH	Queen Elizabeth Central Hospital	Blantyre, Malawi
QM	Qhakaza Mbokodo	Ladysmith, South Africa
RHRU-E	Reproductive Health and HIV Research Unit (Edendale)	Pietermaritzburg, South Africa
RHRU-O	Reproductive Health and HIV Research Unit (Orange Farm)	Orange Farm, South Africa
RHRU-S	Reproductive Health and HIV Research Unit (Soweto)	Soweto, South Africa
RHRU-Y	Reproductive Health and HIV Research Unit (Yeoville)	Johannesburg, South Africa
RK KHAN	R.K. Khan Hospital	Chatsworth, South Africa
SRC	Setshaba Research Centre	Soshanguve, South Africa
THAI	Thailand MOPH–U.S. CDC Collaboration	Bangkok, Thailand
UAB	University of Alabama at Birmingham	Birmingham, USA
UN	University of Nairobi, Department of Community Health, Centre for HIV Prevention & Research	Kibera, Kenya
UNC	University of North Carolina Project	Lilongwe, Malawi
UPENN	University of Pennsylvania	Philadelphia, USA
UPITT	University of Pittsburgh	Pittsburgh, USA
UPR	University of Puerto Rico	San Juan, Puerto Rico
USF	University of South Florida	Tampa, USA
UTH	University Teaching Hospital (MDP 301 Mazabuka site)	Mazabuka, Zambia
UVRI	Medical Research Council/ Uganda Virus Research Institute, Uganda Research Unit on AIDS	Entebbe, Uganda
UZ/UCSF	University of Zimbabwe-University of California, San Francisco	Harare and Chitungwiza, Zimbabwe
YRG	YRG Care	Chennai, India

Abbreviations Used in this Document

AACTG	Adult AIDS Clinical Trials Group
ACASI	Audio Computer-Assisted Self Interview
ACTG	AIDS Clinical Trials Group
AMREF	African Medical and Research Foundation
ANC	Antenatal care
ANRS	Agence Nationale de Recherche sur le Sida
ATN	Adolescent Medicine Trials Network
BREC	Biomedical Research Ethics Committee
CAB	Community Advisory Board
CAP	College of American Pathologists
CBO	Community-based Organization
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CHA	Centre Hospitalier Affilié Universitaire de Québec
CIDA	Canadian International Development Agency
CIDRZ	Centre for Infectious Disease Research Zambia
CLS	Contract Lab Services
COMREC	College of Medicine Research and Ethics Committee
CRESAC	Centre Regional d'Evaluation en Santé et Accréditation
CRF	Case Report Form
CRI-IDL	Children's Research Institute – Immunodiagnostics Lab
CRO	Contract Research Organization
CS	Cellulose sulfate
CTU	Clinical Trials Unit
DAIDS	Division of AIDS (NIAID, US NIH)
DFID	UK Department for International Development
DHAP	Division of HIV/AIDS Prevention
DOH	Department of Health
DOHMH	Department of Health and Mental Hygiene
DOPH	Department of Public Health
DSMB	Data Safety Monitoring Board
EC	European Commission
EDCTP	European and Developing Countries Clinical Trials Partnership
FHI	Family Health International
FSW	Female sex worker
GCLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
HPRU	HIV Prevention Research Unit
HPTN	HIV Prevention Trials Network
HVTN	HIV Vaccine Trials Network
IATA	International Air Transport Association
IAVI	International AIDS Vaccine Initiative
ICH	International Conference on Harmonisation
ICMR	Indian Council of Medical Research
IDU	Injection drug user
IMPAACT	International Maternal Pediatric Adolescent AIDS Clinical Trials Group
IND	Investigational New Drug
IPM	International Partnership for Microbicides
IRB	Institutional Review Board
ITM	Institute of Tropical Medicine
LDMS	Laboratory Data Management System
LRF	Laboratory Request Forms
LSHTM	London School of Hygiene and Tropical Medicine
MCC	Medicines Control Council
MDP	Microbicides Development Programme
MOH	Ministry of Health
MOPH	Ministry of Public Health
MOU	Memorandum of Understanding
MRC	Medical Research Council
MSM	Men who have sex with men
MTN	Microbicide Trials Network
NAAT	Nucleic acid amplification test
NGO	Non-governmental Organization
NHLS	National Health Laboratory Service
NHSRC	National Health Sciences Research Committee
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIMR	National Institute for Medical Research
PACTG	Pediatric AIDS Clinical Trials Group
PBMC	Peripheral Blood Mononuclear Cell
PC	Population Council
PHC	Primary Health Care
QA/QC	Quality Assurance/Quality Control
QASI	Quality Assurance Systems International
RCPA	Royal College of Pathologists of Australasia
REC	Research Ethics Committee
RSID	Rapid Stain Identification
SAE	South African National Accreditation System
SCHARP	Statistical Center for HIV/AIDS Research and Prevention
SOP	Standard Operating Procedure
SPARTAC	Short Pulse Antiretroviral Therapy at Acute Infection
TFDA	Tanzanian Food and Drug Regulatory Authority
UCSF	University of California, San Francisco
UKNEQAS	UK National External Quality Assessment Service
USAID	United States Agency for International Development
USFDA	United States Food and Drug Administration
VCT	Voluntary Counseling and Testing
VQA	Virology Quality Assessment
WHO	World Health Organization
ZINQAP	Zimbabwe National Quality Assurance Programme

Table 1: General Facilities

Note: All sites have clean water and electricity.

Site	Back-up generators	Internet access/email	Dedicated computers for trial	International phone lines	Other services
ARCA	Yes	Yes	Yes	Yes	-70°C freezers, multiple centrifuges including refrigerated centrifuges, facilities for processing PBMCs
BLHC	No	Yes	Yes	Yes	Colpolscope, DataFax machine
BPCRS	Yes	Yes	Yes	Yes	Laboratory services
CAPRISA	Yes	Yes	Yes	Yes	DataFax, comprehensive AIDS treatment services
CIDRZ	Yes	Yes	Yes	Yes	Complies with NIH/NIAID/DAIDS standards for conduct of clinical trials, GCLP trained lab staff , GCP trained clinic staff, laboratory services, incinerator for biohazardous material disposal, DataFax , printers, photocopiers, air conditioners, conference call equipment , adjacent to AIDS treatment/care center
DTHF	No	Yes	Yes	Yes	Laboratory services
EC	Yes	Yes	Yes	No	No data provided
FEE	Yes	Yes	Yes	Yes	No data provided
ICRH	Yes	Yes	Yes	Yes	Colposcopy services, laboratory facilities
INMENSA	Yes	Yes	Yes	Yes	Complies with NIH/NIAID/DAIDS standards for conduct of clinical trials; on-site data management center and research lab with capacity to isolate PBMC and run hematology, biochemistry, STI, CD4+ cell count, HIV serology, viral load and genotyping resistance tests
ISIP	Yes	Yes	Yes	Yes	DataFax and fax machines, printers, photocopiers, air conditioners, TVs, video recorder, conference call equipment, remote computer server. ~30 trained staff with 2+ yrs GCP and clinical trial experience
IST	Yes	Yes	Yes	Yes	PCR laboratory
KCMC	Yes	Yes	Yes	Yes	Colposcopy services, laboratory facilities
KEMRI	Yes	Yes	Yes	Yes	GCLP lab, DataFax, GCP-trained staff
LSHM	No	Yes	Yes	Yes	Laboratory facilities; have already done two Phase 1/2 microbicide studies
MCR	Yes	Yes	Yes	Yes	Laboratory services
MDP MAW	Yes	Yes	Yes	Yes	No data provided
MIRIAM	Yes	Yes	Yes	Yes	Have already done four Phase 1 microbicide studies
MRC DUR	Yes	Yes	Yes	No	Colposcopy services and laboratory facilities
MRC HLA	Yes	Yes	Yes	Yes	No data provided
MUDHOL	Yes	Yes	Yes	Yes	No data provided
MUMS	Yes	Yes	Yes	Yes	Lab facilities, AIDS treatment/care centers
NARI	Yes	Yes	Yes	Yes	No data provided
PHIVA	No	Yes	Yes	Yes	Laboratory services
PU	Yes	Yes	Yes	Yes	Colposcopy services, laboratory facilities

Site	Back-up generators	Internet access/email	Dedicated computers for trial	International phone lines	Other services
QECH	Yes	Yes	Yes	Yes	Colposcopy services, laboratory facilities, GCLP lab, GCP-trained staff, easy referral to/for AIDS treatment
QM	No	Yes	Yes	Yes	Laboratory facilities
RHRU-E	No	Yes	Yes	Yes	Laboratory facilities
RHRU-O	Yes	Yes	Yes	Yes	All the necessary clinic equipment to conduct clinical trials in the field of HIV prevention; world-class back up laboratory within a short distance of the clinical site
RHRU-S	Yes	Yes	Yes	Yes	All the necessary clinic equipment to conduct clinical trials in the field of HIV prevention; world-class back up laboratory within a short distance of the clinical site
RHRU-Y	No (in process of buying one)	Yes	Yes	Yes	Colposcopy services, laboratory facilities
RK KHAN	Yes	Yes	Yes	Yes	DataFax and fax machines, printer, photocopier, air conditioners, TV, ~45 trained staff with GCP and clinical trial experience
SRC	Yes	Yes	Yes	Yes	No data provided
THAI	Yes	Yes	Yes	Yes	No data provided
UAB	Yes	Yes	Yes	Yes	No data provided
UN	Yes	Yes	Yes	Yes	Back up generator at the laboratory
UNC	Yes	Yes	Yes	Yes	Colposcopy and lab facilities
UPENN	Yes	Yes	Yes	Yes	Phase 1, 2/2B experience, colposcopy, laboratory facilities, DataFax
UPITT	Yes	Yes	Yes	Yes	No data provided
UPR	Yes	Yes	Yes	Yes	No data provided
USF	Yes	Yes	Yes	Yes	Lab facilities, colposcopy, DataFax
UTH	Yes	Yes	Yes	Yes	No data provided
UVRI	Yes	Yes	Yes	Yes	Data management systems in place and clinical and safety labs
UZ/UCSF	Yes	Yes	Yes	Yes	No data provided
YRG	Yes	Yes	Yes	Yes	State-of-the-art lab and well-trained teams for clinical/behavioral trials

Table 2: Human Resources and Technical Requirements

Note: All sites have GCP-trained clinical staff, GCP-compliant study procedures, an established process for the import/export of trial materials (where applicable), and SOPs for management of test materials and adverse events (if applicable).

Site	Dedicated clinical trials administrator	Research pharmacy	Does research pharmacy have:				Research pharmacist
			limited access?	back-up power?	security?	temp-monitored refrigerator or freezer to store test materials	
ARCA	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BLHC	Yes	Yes	Yes	Yes	Yes	Yes	Yes
BPCRS	Yes	Yes	Yes	Yes	Yes	Yes	Yes
CAPRISA	Yes	Yes	Yes	Yes	Yes	Yes	Yes
CIDRZ	Yes	Yes	Yes	Yes	Yes	Yes	Yes: Pharmacy technicians with pharmacist oversight
DTHF	Yes	Yes	Yes	Yes	Yes	Yes	Yes
EC	No	No	N/A	N/A	N/A	N/A	No
FEE	Yes	Yes	Yes	Yes	Yes	Yes	Yes
ICRH	Yes	Yes	Yes	No	No	Yes	Yes
INMENSA	Yes	Yes	Yes	Yes	Yes	Yes	Yes
ISIP	Yes	Yes	Yes	Yes	Yes	No	Yes
IST	No, but one administrator manages all projects.	No, but access to refrigeration and back-up power is available in a nearby lab.					No: trained nurse
KCMC	Yes	Yes	Yes	Yes	Yes	Yes	Yes
KEMRI	Yes	Yes	Yes	Yes	Yes	Yes	Yes
LSHM	Yes	No	N/A	N/A	N/A	N/A	No
MCR	Yes	No: site is only conducting incidence studies at this time, but temp-monitored refrigerator/freezer to store materials available.					
MDP MAW	No, but each trial has study coordinator and shares financial/ administrative support	Yes	Yes	Yes	Yes	Yes	Yes
MIRIAM	Yes	Yes	No data provided				Yes
MRC DUR	Yes	Yes	Yes	Yes	Yes	Yes	Yes
MRC HLA	Yes	Yes	Yes	Yes	Yes	Yes	Yes
MUDHOL	Yes	Yes	Yes	Yes	Yes	Yes	No
MUMS	Yes	Yes	Yes	Yes	Yes	Yes	Yes
NARI	Yes	Yes	No data provided				Yes

Site	Dedicated clinical trials administrator	Research pharmacy	Does research pharmacy have:				Research pharmacist
			limited access?	back-up power?	security?	temp-monitored refrigerator or freezer to store test materials	
PHIVA	Yes	No: site is only conducting incidence studies at this time, but temp-monitored freezer (-40°C) available.					
PU	Yes	No: site is only conducting incidence studies at this time.					
QECH	Yes	Yes	Yes	Yes	Yes	Yes	Yes
QM	Yes	No: site is only conducting incidence studies at this time, but temp-monitored refrigerator/freezer to store materials available.					
RHRU-E	Yes	No: site is only conducting incidence studies at this time, but temp-monitored refrigerator/freezer to store materials available.					
RHRU-O	Yes	Yes	Yes	Yes	Yes	Yes	Yes
RHRU-S	Yes	Yes	Yes	Yes	Yes	Yes	Yes
RHRU-Y	No	The site is able to store study drug and is in the process of installing generator power, and has state of the art security including electric fencing and alarms					Yes
RK KHAN	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SRC	Yes	Yes	Yes	Yes	Yes	Yes	No
THAI	Yes	No	N/A				No
UAB	Yes	Yes	Yes	Yes	Yes	Yes	Yes
UN	Yes	Yes	Will be set up by January 2008				No
UNC	Yes	Yes	Yes	Yes	Yes	Yes	Yes
UPENN	Yes	Yes	No data provided				Yes
UPITT	Yes	Yes	Yes	Yes	Yes	Yes	Yes
UPR	Yes	Yes	No data provided				Yes
USF	Yes	Yes	Yes	Yes	Yes	Yes	Yes
UTH	Yes	Yes	Yes	Yes	Yes	Yes	Yes
UVRI	Yes	Yes	Yes	Yes	Yes	Yes	Yes
UZ/UCSF	Yes	Yes	Yes	Yes	Yes	Yes	Yes
YRG	Yes	Yes	No data provided				Yes

Table 3: Communications Plan and Community Involvement

Site	Established communications/ media plan	Dedicated Communications Officer	CAB (or other community research support group)
ARCA	Yes (study specific)	Yes (Enrollment Coordinator)	Yes
BLHC	Yes	IoR is point of contact for media	Yes
BPCRS	Yes	Yes	Yes
CAPRISA	Yes	No	Yes
CIDRZ	Yes	No	Yes
DTHF	Yes	Yes	Yes
EC	Yes	Yes	Yes
FEE	Yes	Yes	Yes
ICRH	No	No	Yes
INMENSA	Yes	Yes	Yes
ISIP	No: Following the HPRU's experience with the closure of the CONRAD trial sites, the HPRU understands the value of a Media Relations Plan and is currently developing a plan with assistance from the newly-appointed HPRU Media Officer.	No: All media-related queries are directed by the Study Project Leader to the Unit Director and the Media Officer.	No: A decision was made to avoid formation of a formal CAB to minimize problems that may have arisen due to differing political opinions. A network of care and key stakeholders are in constant communication with the site via the site's community liaison officer and field team.
IST	Site complies with sponsors' plan	Yes (in Quebec)	No permanent CAB; established for each trial
KCMC	No data provided	Yes	Yes
KEMRI	Yes	No	Yes
LSHM	Yes	Yes	Yes
MCR	No	No	Yes
MDP MAW	Yes	No, but vacant post expected to be filled in 1-2 months. Site has a community liaison officer who deals with local communication issues and community communications.	Yes
MIRIAM	Yes	Yes	Yes
MRC DUR	Yes	Yes	No
MRC HLA	Yes	No	Yes
MUDHOL	Yes	No	Yes
MUMS	No	No	Peer leaders, behavioral scientists
NARI	Yes	Yes	Yes
PHIVA	Yes	Yes	No: In the initial stages of conducting incidence studies-in the process of establishing CABs
PU	No data provided	Yes	Yes
QECH	Yes	Yes	Yes
QM	Yes	Yes	No: In the initial stages of conducting incidence studies-in the process of establishing CABs

Site	Established communications/ media plan	Dedicated Communications Officer	CAB (or other community research support group)
RHRU-E	No	Yes	No: In the initial stages of conducting incidence studies-in the process of establishing CABs
RHRU-O	Yes	Yes (in the process of recruiting)	Yes
RHRU-S	Yes		Yes
RHRU-Y	Yes		Yes
RK KHAN	Yes	No	Yes
SRC	Yes	Yes	Yes
THAI	Yes	No	Yes
UAB	In development	Yes	Yes
UN	In development	In development	Yes
UNC	Yes	Yes	Yes
UPENN	Yes	Yes	Yes
UPITT	No	No	Yes
UPR	Yes	Yes	Yes
USF	Yes	Yes	Yes
UTH	Yes	Yes	Yes
UVRI	Yes	Yes	Yes
UZ/UCSF	Yes	Yes: Sites have a well-established media and communications program with a media primary point person and backup. There are specific persons appointed for interviews and press releases.	Yes: Sites have CAB as well as a Community Liaison Officer who mediates communication between the research team and the community. The CAB members and research representatives hold bimonthly meetings.
YRG	Yes	Yes	Yes

Table 4: HIV Prevalence and Incidence

Site	HIV prevalence	Assessment method for prevalence	HIV incidence	Assessment method for incidence
ARCA[1]	Last official full-year data available from the State of GA are from 2006. 2007 data will be available mid-2008. The highest HIV non-AIDS rates occurred among residents of Fulton and DeKalb Health Districts. Fulton Health District: HIV non-AIDS rate - 35.4 per 100,000 population; AIDS rate - 18.7 per 100,000. DeKalb Health District: HIV non-AIDS rate - 34.8 per 100,000; AIDS rate - 9.6 per 100,000. ARCA HIV testing program had HIV prevalence rates ranging from 1.1 (women) to 14.2 (African-American MSM). Data are from the State of GA HIV/AIDS Reporting System database and are reported by date of diagnosis. Data from the last full-year are published in the GA HIV/AIDS Surveillance Summary. Data from ARCA are unpublished (as of Dec 31, 2007) from the ARCA HIV Testing Database.		No reliable studies of HIV incidence in the metropolitan Atlanta area or in GA. State of GA Laboratory does not yet offer detuned HIV assays or pooled HIV-RNA PCR testing. The State relies on mathematical modeling from CDC estimating that 25% of those with HIV in the state are undiagnosed. All references to HIV or AIDS "incidence" in the State database actually refer to new diagnoses, not true incidence of infection. Data for new diagnoses of HIV are as follows: 67% male (34% MSM, 7% IDU or MSM/IDU, 7% high-risk heterosexual contact, 51% no risk factor); 33% female (61% no risk factor, 25% high-risk heterosexual contact, 7% reported IDU); 79% non-Hispanic African-American, 16% non-Hispanic white, 4% Hispanic. Most recently published data are from the GA HARS database; only 2006 data have been published to date.	
BLHC	Prevalence in South Bronx neighborhood of Highbridge-Morrisania (2.3%) almost double overall NYC rate (1.2%)	HIV Surveillance and Epidemiology Program, NYC DOHMH, 2003	37 per 100,000 women in Highbridge-Morrisana	HIV Surveillance and Epidemiology Program, NYC DOHMH, 2003
BPCRS	22.83%	IPM100 study currently underway at site	Unknown, site busy with incidence study	
CAPRISA	39.4% in pregnant women in the Vulindlela community in 2006	Assessed as part of CAPRISA's ongoing epidemiological studies—annual, anonymous, cross-sectional surveys among all first-visit antenatal clinic attendees utilizing 7 primary care clinics between 2001 and 2006 (in concert with the national survey each year to enable direct comparison of the data)	8.5 (CI: 4.0-12.9) per 100 women-years (in young women under age 30)	Follow-up of cohort of 360 young women
CIDRZ	19-21% in non-pregnant women aged 16-30	Pre-screening VCT for HPTN 035 of 707 women (Jun 06 to Jul 07)	2.6% in women aged 16-49	HPTN 055 cohort of 240 women (Mar 03 to Oct 05)
DTHF	Adults(15+): 23%	Desmond Tutu HIV Centre study, 2005	Adults(16-40 yrs): 6.7%	Cohort study among 200 adults, 2005-06
EC	18%	Data obtained from screening period of Phase 3 Carraguard trial, 2004 to Mar 2007. Participants screened for HIV and other inclusion/exclusion criteria.	2.8%	Number of seroconverters enrolled in the Carraguard trial, tested at quarterly follow up visits
FEE	18.6% in MSM	Cross-sectional study survey among high-risk MSM in Guayaquil-Ecuador (570 MSM) as part of a comparative study with 4 Peruvian cities (2,608 MSM	4.8 per 100,000 person-years	Same study as prevalence estimate. Early infection and incidence were estimated by the BED EIA

Site	HIV prevalence	Assessment method for prevalence	HIV incidence	Assessment method for incidence
		enrolled in 5 cities). Accrual expected to be 4 months to enroll 570 men. Men who referred not knowing their HIV serostatus or not having an HIV test during the previous 12 months were contacted at previously MSM venues and referred to study clinic. Study outreach work promoted the self-exclusion of HIV-positive men. HIV-1/2 antibodies screened by Determine HIV 1/2 Rapid Test and confirmed with Western Blot. Study conducted Jan-Jun 2005.		according to the manufacturer's instructions. Study conducted Jan-Jun 2005.
ICRH	35% among most-at-risk populations including female and male sex workers; 11% among postpartum women	Various epidemiological cross-sectional studies have been conducted	An estimated 6.9% (95% CI= 3.4-13.7) in Chaani among FSWs	Prospective cohort study among 400 HIV-negative FSWs in Chaani and Kisauni areas
INMENSA	In Lima: MSM: 23%; FSW: 1.2%; pregnant women: 0.4%	Convenience sampling sentinel surveillance surveys conducted in 2004.	Highest observed HIV incidence among MSM was 6.2 new cases per 100 person-years (2003-2004).	Prospective cohort of high-risk MSM conducted in Lima during 2003-2004.
ISIP	40.04 %	Phase 3 Carraguard trial: prevalence assessed by 2 HIV rapid tests in women aged 16-66 who were screened between Oct 2004 and Jun 2006	Information will be released soon	Post enrollment, incidence assessed by the same HIV testing method as at screening every 3 months within study
IST	30%	Recruitment in CS trial (2005-06)	5 per 100 person-years	Follow-up of participants within CS trial (2005-07)
KCMC	10.3%	Moshi Infertility Survey 2002-2003	Unknown	N/A
KEMRI	Women: 25%; men: 15%	Random population-based survey in Kisumu	Young men (18-24): 3%; young women estimated 4-5%	Recent male circumcision trial and point-prevalence from random population-based survey
LSHM	7%	Official local and UNAIDS data	7% (according UNAIDS report)	Official local and UNAIDS data
MCR	29.9% based on antenatal clinic data in North West Province, Apr 2007; 24.3% based on % of HIV positive participants screened in IPM100 cross-sectional study, Nov 2007		Unknown, site busy with incidence study	
MDP MAW	Approximately 25% among cohort for feasibility study (high risk target population)	Data collected 2002-03 for feasibility study – baseline prevalence among women enrolled in the feasibility study	Approximately 2.5 per 100 person-years	Data from feasibility study for the trial (Jul 02 to Dec 04)

Site	HIV prevalence	Assessment method for prevalence	HIV incidence	Assessment method for incidence
MIRIAM	1-10% in high risk groups	Community studies of IDU and high-risk women	2%	Prior studies of high-risk cohorts
MRC DUR	39.1%	Data from DOH	Unknown	N/A
MRC HLA	34.5%	HPTN 055 (completed Dec 04): longitudinal study involving 240 participants with 1 year follow-up, 526 participants screened	5.5%	HPTN 055 (completed Dec 04): longitudinal study involving 240 participants with 1 year follow-up, 526 participants screened
MUDHOL	2.9% in the general population	General population-based survey conducted in 2005. Annual Sentinel Surveillance conducted among antenatal women (also demonstrates HIV prevalence between 2-3%)	Estimated: 0.6%	Based on HIV incidence testing among seropositive samples from the general population based survey, using a detuned assay
MUMS	7.1% (national)	National surveillance 10-12% for Kampala area (through routine antenatal testing)	1.55	HIV hormonal study
NARI	No data provided	No data provided	No data provided	No data provided
PHIVA	30-60%	Wide range of studies done	Predicted 6-8%	N/A
PU	24%	Cross-sectional survey	Unknown	N/A
QECH	General population: 14%.; Pregnant women: 20-30%.	MOH's national surveillance program;	4-5 per 100 person years	HPTN 016 data; Metro Study
QM	40%	Information obtained from Provincial primary health clinics	Unknown, site busy with incidence study	
RHRU-E	39.1% (KZN)	National HIV and seroprevalence survey in South Africa 2006	Predicted at 6-8%	N/A
RHRU-O	25%	Present screening for a large Phase 3 trial; over 3,300 women screened	4-5%	Present HIV prevention trial; 2,300 women enrolled to date
RHRU-S				
RHRU-Y	+/- 30-40%	Information gathered from previous trials in surrounding communities	4%	Information gathered from previous trials in surrounding communities
RK KHAN	39.7%	HPTN 055: longitudinal study involving 240 participants with 1 year of follow up completed Dec 2004. 561 participants screened.	5.0%	HPTN 055
SRC	24.5%	Data obtained from screening period of Phase 3 Carraguard trial 2004 to Mar 2007. Participants screened for HIV and other inclusion/exclusion criteria.	3%	Number of seroconverters enrolled in the Carraguard trial, tested at quarterly follow up visits.
THAI	40%	Annual surveillance by MOPH	3.4% among IDU participants in Phase 3 vaccine trial (complete 2003)	

Site	HIV prevalence	Assessment method for prevalence	HIV incidence	Assessment method for incidence
UAB	4,286 cases in Jefferson County	Data as reported by the Alabama DOPH (cumulative as of 04/06/07)	32.56 per 100,000 in Jefferson County from 01 Jan-31 Dec 2006; 20.69 per 100,000 in Jefferson County, Alabama from 01 Jan-31 Mar 2007; Data reported by the Alabama DOPH	
UN	8%	National Survey (2006)	4.5%	Cohort study 3 years ago
UNC	12%	Women screened for HPTN 035	2.5%	HPTN 035 screening; work in sexually-transmitted infection clinic
UPENN	No data provided	No data provided	2.03/100 person-years in women; 4.55/100 person-years among African American women	HPTN 037 data of injection drug users and their drug using or sexual partners
UPITT	N/A	N/A	N/A	N/A
UPR	No data provided	No data provided	No data provided	No data provided
USF	18.2/100,000 in 20-24 year-old age group	Population estimates, DOH	No data provided	No data provided
UTH	16%	From MDP 301 database	3.8%	From MDP 301 database
UVRI	8%	General population cross sectional survey of approximately 1,200 adults (between 2004-2005)	1.2 per 100 person-years in general population and 4.3 per 100 person-years among HIV negative individuals in discordant couples	Data obtained from ~ 1200 HIV negative adults recruited in a 2-year feasibility study and seen every 3 months (2005-06). In addition, 500 HIV negative individuals in HIV discordant couples seen every 3 months (currently ongoing).
UZ/UCSF	15% (adults 15-49 yrs) and 22% among childbearing women	2007 rates from Zimbabwe MOH	2.6-4% per year in the context of cohort studies or clinical trials of primarily married women, with intensive condom counseling during the study.	Prospective studies from 1999-2006 among non-pregnant women of childbearing age, assessed by 2 rapid tests and confirmed by ELISA and clinical trials of female controlled methods.
YRG	ANC rate is estimated at 0.30% in the latest government of India surveillance report.		No incidence study has been conducted to substantiate data.	

[1] Official data from the State of GA are limited by the lack of HIV name-based reporting until recently and the absence of a system for estimating the incidence of HIV infection. The following description from the Georgia HIV/AIDS Surveillance Summary (Georgia HIV/AIDS Surveillance Summary, data through Dec 31, 2006. State of Georgia Department of Health and Human Services Division of Public Health) provides further explanation: "Unlike AIDS reporting, which began in the early 1980s, reporting HIV infection by name is relatively new in Georgia. Confidential name-based HIV reporting began on December 31, 2003. As a result, the HIV surveillance system is still immature and the numbers of HIV (non-AIDS) cases presented underestimate the true incidence and prevalence of HIV (non-AIDS) in the population. In 2006, staffing changes limited the capacity of the GDPH HIV/AIDS Surveillance Unit to perform active surveillance of AIDS cases. As a result, the numbers of AIDS cases presented underestimate the true incidence and prevalence of AIDS in the population in 2006."

Table 5: Potential Participant Population

Site	# participants that could be recruited for microbicide or PrEP trial	Age distribution	Significant proportion involved in commercial sex work	Predominant mode of transmission	Willingness to participate in a clinical trial
ARCA	Site enrolled 121 MSM (40% men of color) in the CDC US PrEP trial of the safety of tenofovir. Had the trial been managed differently, the site could have enrolled many more. Would expect to be able to enroll a minimum of 10-20 pts/month in a well-designed microbicide or PrEP trial with adequate patient incentives, adequate funding for community outreach, the ability to recruit through the internet, an appropriate and vigorous marketing strategy, and minimal obstacles to rapid regulatory review. Given the above caveats, the site would expect to be able to enroll between 100-150 men and women in a PrEP trial over a 12 month period. Site could rapidly enroll microbicide trials for both women and men, and has existing networks of HIV-negative women and men who are interested in prevention trials. Site has excellent and rapid response to studies involving STI testing for men and women, enrolling 150 men and women in six months for a recent study of STI testing assays.	• 15-19: 5% • 20-29: 30% • 30-39: 30% • 40-49: 20% • 50-59: 10% • 60+: 5%	No (but able to specifically recruit that population if needed)	MSM and heterosexual women	The site was able to attain 40% enrollment of men of color in a PrEP trial with 2 year follow-up. This required a focused effort on education and outreach, however it resulted in a higher level of clinical trial awareness among this population. During the outreach for this trial in MSM, site collected contact information for over 600 HIV-negative MSM who said they were interested in learning more about clinical trials. In a recent trial of STI testing assays, the site enrolled 150 men and women in six months. The study required repeated urethral swabs for men and cervical swabs for women.
BLHC	50 to 75	• 15-19: 5% • 20-29: 40% • 30-39: 10% • 40-49: 40% • 50-59: 5%	Yes	Sexual transmission	Not assessed
BPCRS	300+	• 15-24: 19.7% • 25-44: 32.7% • 45-64: 14.7% • 65+: 4.4%	No	Heterosexual transmission	Being assessed by IPM in current epidemiology study in Mbekweni; response has been positive, although initially

Site	# participants that could be recruited for microbicide or PrEP trial	Age distribution	Significant proportion involved in commercial sex work	Predominant mode of transmission	Willingness to participate in a clinical trial
					the community was hesitant to come forward.
CAPRISA	1,000	Ages 20 to 49	No	Heterosexual transmission	Assessed through focus group discussions and CAB consultation.
CIDRZ	250-350	Majority between 15 and 39; fewer between 40 and 49; few 50 +	No	Heterosexual transmission	Completion of accrual targets within required time frame for HPTN 055 and HPTN 035 for this population. Retention over 95%.
DTHF	500-1,000	Ages 15-49	No	Heterosexual transmission	A history of conducting clinical research studies in this community is present. Functioning CAB in the community. Interest in research is expressed at CAB meetings; formally asked this in connection to participation in vaccine clinical trials; very positive response.
EC	1,000-2,000	No data provided	Unknown	Vaginal transmission	Previous trials have shown ease of recruitment of more than 2,000 women.
FEE	500	• 15-19: 100 • 20-29: 300 • 30-39: 50 • 40-49: 50	Yes	Unprotected anal intercourse	No data provided
ICRH	Approximately 500	• 15-19: 5% • 20-29: 49% • 30-39: 30% • 40-49: 13% • 50-59: 2% • 60+: 0.5%	Yes	Heterosexual transmission	93% retention of the study participants was achieved after 12 months of follow-up in a prospective cohort. The study was designed to assess the preparedness of the participants for future microbicides studies.
INMENSA	Site has capacity and experience to	• 15-19: 15%*	Yes	Homosexual	Survey conducted in 2006

Site	# participants that could be recruited for microbicide or PrEP trial	Age distribution	Significant proportion involved in commercial sex work	Predominant mode of transmission	Willingness to participate in a clinical trial
	enroll low- and high-risk participants in small, medium and large clinical trials. A total of 500 high-risk MSM will be enrolled in iPrEx in the upcoming year.	• 20-29: 30% • 30-39: 25% • 40-49: 15% • 50-59: 10% • 60+: 5% * legal consenting age: 18		transmission	among 1,214 high-risk MSM showed 83.0% willingness to participate in a PrEP efficacy trial. Feasibility studies among MSM to evaluate willingness to participate in microbicide trials are underway.
ISIP	For the Phase 3 Carraguard study, 2,962 women were screened to enroll 1,485 HIV negative women. To obtain this screening number, ~48,200 men/women/children were educated/actively recruited in study recruitment area. The number recruited for future studies will depend on the inclusion/exclusion criteria and sample size.	Target age group should be 18-40. Ethical approval for inclusion of ages 16-18 could be beneficial to women in this age group, who are more at risk and in many cases most in need of interventions, but are often excluded from studies due to ethical limitations and the need for parental consent in addition to child assent.	No	Heterosexual transmission	Not directly but experience in recruitment of clinical trial naïve participants in the catchment area and interest in participation in subsequent studies following close out from one study has been positive.
IST	200 to 300	• 15-19: 10% • 20-29: 50% • 30-39: 30% • 40-49: 10%	Yes	Sexual transmission	Positive-met 80% of target recruitment in CS trial.
KCMC	Approximately 500	No data provided	Yes	Heterosexual transmission	Retention on previous studies good.
KEMRI	Site will be enrolling 50 couples in a PrEP trial; between several sites could enroll several thousand women in a microbicide trial.	• 15-19: 25% • 20-29: 40% • 30-39: 15% • 40-49: 10% • 50-59: 8% • 60+: 3%	No	Heterosexual transmission	Ongoing HSV-2 suppression trial, Phase 1 microbicide trial, planned PrEP trial in discordant couples, trial among young men.

Site	# participants that could be recruited for microbicide or PrEP trial	Age distribution	Significant proportion involved in commercial sex work	Predominant mode of transmission	Willingness to participate in a clinical trial
LSHM	1,500 women	In Part A, mean age of participants is 27-30, depending on study arm. Breakdown by age group: • 15-19: 1 • 20-29: 139 • 30-39: 90 • 40-49: 29 • 50-59: 2	No	Sexual transmission	Experience with two Phase 1/2 trials and HSV-2 suppression trial.
MCR	800-1,000	• 15-34: 66,281 males, 66,231 females • 35-64: 52,638 males, 46,393 females • 65+: 6,565 males, 10,298 females	Unknown	Sexual transmission and mother-to-child	Results pending
MPD MAW	1,200	• 15-19: approx 7.3% • 20-24: 22.6% • 25-34:45.2% • 35+: 25%	Not formally, but a significant proportion supplement income through transactional sex (though less often financial transactions)	Heterosexual transmission	Feasibility study conducted with strong community component showed that study population was willing to participate in a microbicide clinical trial.
MIRIAM	At least 200, since site has recruited such a cohort for the Vaccine Preparedness Studies.	• 15-19: 10% (don't enroll below 18) • 20-29: 20% • 30-39: 20% • 40-49: 20% • 50-59: 20% • 60+: 20%	Yes	Heterosexual transmission	High levels of willingness (Mason et al).
MRC DUR	Thousands	Ages 20-29	No	Heterosexual transmission	Retention is high.
MRC HLA	Up to 200	• 15-19: 15%	No	Heterosexual	Not assessed

Site	# participants that could be recruited for microbicide or PrEP trial	Age distribution	Significant proportion involved in commercial sex work	Predominant mode of transmission	Willingness to participate in a clinical trial
		• 20-29: 30% • 30-39: 25% • 40-49: 20% • 50-59: 10%		transmission	
MUDHOL	200 to 300	• <20: 10% • 20-29: 60% • 30-39: 22% • 40 &>: 8%	Yes	Sexual transmission	Phase 3 trial of CS implemented in the site had to be withdrawn on the basis of preliminary results. The survey had just begun; refusal rate <5% among participants who had volunteered for screening.
MUMS	1,500 or more depending on the type of population being studied.	Population is between 20 and 39 years of age	Yes	Heterosexual transmission	Through previous microbicide trial; many women readily accepted.
NARI	No data provided	No data provided	No data provided	No data provided	No data provided
PHIVA	300+	Ages 15-39	No	Heterosexual transmission	Currently being assessed
PU	Approximately 500	No data provided	Yes	Heterosexual transmission	Retention on previous and current study good.
QECH	Site has vast experience in undertaking clinical trials. There is a considerable population to recruit for microbicide or PrEP trials.	18-35 years	No data provided	Heterosexual transmission	Site has plenty of experience and has done multiple clinical trials of phase 1-3 clinical trials, including vaginal microbicide trials.
QM	300+	Ages 15-39	No	Heterosexual transmission	Currently being assessed
RHRU-E	300+	Ages 15-39	No	Heterosexual transmission	Currently being assessed
RHRU-O	400	Mean age for participants in present study is 23; sites are able to recruit participants in all age groups	No	Heterosexual transmission	Each site has enrolled 1,200 into the MDP 301 trial. Both sites have a functioning CAB and weekly community radio slots to engage the community in the research process.
RHRU-S			No	Heterosexual transmission	
RHRU-Y	The population in the surrounding	Ages 15-39,	No	Heterosexual	The site has experience

Site	# participants that could be recruited for microbicide or PrEP trial	Age distribution	Significant proportion involved in commercial sex work	Predominant mode of transmission	Willingness to participate in a clinical trial
	inner city suburbs is in the region of 500,000. In addition, Alexandra township is close to the site and very easily accessed by public transport and is home to about 800,000 people. 120 were recruited in Acidform and 400 in HPTN 039.	previous protocols have stipulated ages from 18 to 39. At this point in time it is unlikely that the site's ethics committee will give approval to studies recruiting women under the age of 18 without written consent from the parents.		transmission	in recruiting women into clinical trials with no resistance from the community or from potential participants.
RK KHAN	800	• 15-19: 30% • 20-29: 40% • 30-39: 15% • 40-49: 10% • 50-59: 5%	No	Heterosexual transmission	Not assessed
SRC	Enrolled 2,402 women in the Carraguard trial.	• 15-19: 3-5% • 20-29: 50-60% • 30-39: 40-50% • 40-49: 5%	No	Vaginal sexual transmission	Not assessed
THAI	2,000	• 20-29: 40% • 30-39: 30% • 40-49: 25% • 50-59: 5%	No	Parenteral	Yes
UAB	78 per year	• 15-19: 1% • 20-29: 49% • 30-39: 35% • 40-49: 15%	No	Heterosexual/vaginal sex	Based on the success of recruitment for HPTN 059 (52 participants in 8 months) and the number of participants who upon completion of 059 wished to be contacted in the future regarding participation in upcoming microbicide trials, site foresees continued interest, excitement and willingness to participate

Site	# participants that could be recruited for microbicide or PrEP trial	Age distribution	Significant proportion involved in commercial sex work	Predominant mode of transmission	Willingness to participate in a clinical trial
					in clinical trials, especially as it relates to microbicides and women.
UN	500-600	Unknown	No data provided	Heterosexual transmission	Study training done; data collection starting soon.
UNC	500-700	• 15-19: 10% • 20-29: 60% • 30-39: 30%	No	Sexual transmission	Clinical trials have been conducted at this site since 1999 with no problems encountered.
UPENN	200+ (enrolled 200 in HPTN/MTN 035)	• 18-19: 6% • 20-29: 28% • 30-39: 23% • 40-49: 37% • 50-59: 6%	High risk population is mostly crack smoking women. Many trade sex for drugs or money.	Sexual transmission	Site has recruited, enrolled and retained high-risk women in preparedness studies and clinical trials since 1994.
UPITT	N/A	N/A	N/A	N/A	N/A
UPR	No data provided	No data provided	No data provided	No data provided	No data provided
USF	No data provided	College population	No	Heterosexual transmission	Willing to participate
UTH	8,000	• 15-19: 17% • 20-29: 50% • 30-39: 20% • 40-49: 10% • 50-59: 2% • 60+: 1%	Yes	Heterosexual transmission	Initially assessed during feasibility study; most women expressed interest in joining a research trial. Most women who are now exiting the trial express an interest to continue. Most women who were on the 2% arm of PRO 2000/5 gel have expressed disappointment and wished they could continue the trial. Many girls less than 18 years have come forward hoping to join the study but could not due to minimum age set in protocol.
UVRI	1,000-2,000 women	• 18-19: 6.2% • 20-29: 38.6%	No	Heterosexual transmission	Yes: Ongoing results not yet available

Site	# participants that could be recruited for microbicide or PrEP trial	Age distribution	Significant proportion involved in commercial sex work	Predominant mode of transmission	Willingness to participate in a clinical trial
		• 30-39: 26.8% • 40-49: 18.4% • 50-59: 9.8%			
UZ/UCSF	2,500 were recruited between Sep 2003 and Sep 2005 at 2 clinics for the diaphragm trial – site should be able to recruit the same number for a microbicide/PrEP trial.	• 15-19: 15% • 20-29: 30% • 30-39: 30% • 40-49: 20% • 50-59: 5%	No (significant % are not officially classified as commercial sex workers but there are women who engage in seasonal transactional sex to raise money (e.g., for school fees for their children at the beginning of school terms). There are also what is commonly referred to as "small houses" where a mistress is supported by the partner and receives financial support for sexual favors. Bona fide commercial sex workers will contribute a small % of the potential participants. Exact figures unavailable.	Heterosexual transmission	Preparatory microbicide qualitative studies done in 1998-2000. All participants expressed willingness to take part in a future microbicide study. Since then approximately 2 large cohort studies (HC-HIV and HPTN016A) and 9 clinical trials, many of them Phase 3, (HIVNET 009, HIVNET023, HPTN046, HPTN039, HPTN035, MIRA, HPTN052, RDS, DMS,) have been conducted in this setting. Recruitment/enrollment for clinical trials has achieved targeted numbers within expected timelines.
YRG	Site enjoys substantial rapport with communities and with a strong CAB supported by an excellent outreach team, recruiting and retaining a cohort is not difficult. All staff are trained in GCP, undergo periodic certification on human subjects' involvement in research etc., their outreach initiatives are transparent and with optimal ethical emphasis.	• 15-19: 10% • 20-29: 20% • 30-39: 45% • 40-49: 20% • 50-59: 5%	Yes	Over 85% of transmission is through heterosexual contact only.	Sustained outreach initiatives have assured recruitment of participants for 10+ trials with retention rates of over 90% in each.

Table 6: Testing, Treatment, and Care

Site	PHC	VCT	HIV Tx	ARV therapy	STI testing	STI Tx	Pap smear	Contraceptive counseling	Contraceptive methods	Colpo-scopy	Urine pregnancy testing	Pelvic exam
ARCA[1]	BR	x	BR	CT	x	BR	CT	CT	CT	CT	x	x
BLHC	BR	x	BR	BR	x	x	x	x	x	x	x	x
BPCRS	x, BR	x	BR	BR	x, BR	x, BR	BR	x	x	BR	x	x
CAPRISA	x	x	x	x	x	x	x	x	x	x	x	x
CIDRZ	x, BR	x, BR	x, BR	BR	x	x	x	x	x	BR	x	x, BR
DTHF	x, BR	x	x	x	x, BR	x, BR	x, BR	x	x	x	x	x
EC	BR	x	BR	BR	x	x	x	x	x	BR	x	x
FEE	no	x	no	no	x	x	no	no	no	no	no	no
ICRH	BR	x	x, BR	x, BR	x, BR	x, BR	x	x	x, BR	x	x, BR	x
INMENSA	x	x	x	x	x	x	x	x	x	BR	x	x
ISIP	BR	x	BR	BR	x, BR	x, BR	x, BR	x, BR	x, BR	BR	x	x, BR
IST	x	x	x	x	CT	x	BR	x	x	CT	CT	x
KCMC	BR	x	BR	BR	x	x, BR	x	x	x	x	x	x
KEMRI	x	x	x	x	BR	x	x	x	x	x	x	x
LSHM	BR	x	BR	BR	x	x	x	BR	BR	x	x	x
MCR	BR	x	BR	BR	BR	x	BR	x	x	no	x	x
MDP MAW	no	x	BR	BR	x	x	no	x	x	-	x	x
MIRIAM	x	x	x	x	x	x	x	x	x	x	x	x
MRC DUR	BR	x	BR	BR	x	x	x	x	x	x	x	x
MRC HLA	BR	x	BR	BR	x	x	x	x	x	BR	x	x
MUDHOL	x	x	x	BR	x	x	BR	BR	BR	no	x	x
MUMS	x	x	BR	BR	x	x	x	x	x	BR	x	x
NARI	x	x	x	x	x	x	x	x	x	x	x	x
PHIVA	BR	x	BR	BR	BR	x	BR	x	x	BR	x	x
PU	x, BR	x	BR	BR	x	x	x	x	x	x	x	x
QECH	x	x	x	x	x	x	x	x	x	x	x	x
QM	BR	x	BR	BR	BR	x	BR	x	x	no	x	BR
RHRU-E	BR	x	BR	BR	x	BR	x	x	BR	no	x	x
RHRU-O	BR	BR	BR	BR	BR	x	x	x	x	x	x	x
RHRU-S	BR	BR	BR	BR	BR	x	x	x	x	x	x	x
RHRU-Y	BR	x	BR	BR	x	x	x	x	x	x	x	x
RK KHAN	BR	x	BR	BR	x	x	x	x	x	x	x	x
SRC	BR	x	BR	BR	x	x	x	x	x	BR	x	x
THAI	x	x	BR	BR	x	x	x	x	x	BR	x	x
UAB	x	x	x	x	x	x	x	x	x	x	x	x
UN	x	x	BR	BR	x	x	BR	x	BR	x	x	x
UNC	x	x	x	BR	x	x	BR	x	x	x	x	x
UPENN	x	x	x	x	x	x	x	x	x	x	x	x

Site	PHC	VCT	HIV Tx	ARV therapy	STI testing	STI Tx	Pap smear	Contraceptive counseling	Contraceptive methods	Colpo-scopy	Urine pregnancy testing	Pelvic exam
UPITT	x	x	x	x	x	x	x	x	x	x	x	x
UPR	x	x	x	x	x	x	x	x	x	x	x	x
USF	x	x	x	x	x	x	x	x	x	x	x	x
UTH	BR	x	BR	BR	x	x	BR	x	x	no	x	x
UVRI	x	x	BR	BR	x	x	BR	x	x	BR	x	x
UZ/UCSF	x	x	BR[2]	BR[2]	x	x	x	x	x	x	x	x
YRG	x	x	x	x	x	x	x	x	x	x	x	x

x: on site, BR: by referral, CT: within clinical trials, no: not offered

[1] Over the last 20 years, ARCA has developed a network of primary care collaborators in the private and public sector who can be called upon to get newly diagnosed patients into care and with whom ARCA works for medical care and clinical follow-up. ARCA is capable of performing gynecology procedures on-site if part of research, but for care relies on the primary care network. ARCA has at least 20 clinical trials in progress at any given time, most of which provide one or more antiretroviral drugs.

[2] Sites are conducting research protocols that provide ARV therapy and HIV treatment and care

Table 7: On-Site Laboratory Capacity: Assays

Site	HIV rapid tests	HIV RNA PCR	HIV serology	Hema-tology: CBC	Renal function tests[1]	Liver function tests[2]	CD4+ testing	Viral load testing	STI testing	Urine pregnancy testing	Hepatitis B assay
ARCA[3]	Yes	No	No	No	No	No	No	No	No	Yes	No
BLHC	BLHC has a contracted CLIA/CAP-certified laboratory which can conduct all types of testing listed in this table.										
BPCRS	Yes	No	No	No	No	No	No	No	No	Yes	No
CAPRISA	Yes	No: Testing not conducted on site is done by CAPRISA central lab or contract lab BARC (both in Durban)								Yes	No
CIDRZ	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
DTHF	Yes	No	No	No	No	No	No	No	No	Yes	No
EC	Yes	No	No	No	No	No	No	No	No	Yes	No
FEE	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	No
ICRH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
INMENSA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
ISIP	Yes	No: Site has trained staff to do assays but required lab equipment is not available on site; *T. vaginalis* In Pouch assay was performed and assessed on site for Phase 3 trial.								Yes	No
IST	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
KCMC	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
KEMRI	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes[4]
LSHM	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
MCR	Yes	No	No	No	No	No	No	No	No	Yes	No
MDP MAW	Yes	No	Yes	Yes	No	No	Yes	No	Yes	Yes	No
MIRIAM	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
MRC DUR	Yes	No	No	No	N/A	N/A	No	No	Yes	Yes	No
MRC HLA	Yes	No	No	No	No	No	No	No	No	Yes	No
MUDHOL	Yes	No	Yes	Yes	No	No	No	No	Yes	Yes	No
MUMS	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
NARI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
PHIVA	Yes	No	No	No	No	No	No	No	Yes	Yes	No
PU	Yes	No	No	No	No	No	No	No	Yes	Yes	No
QECH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
QM	Yes	No	No	No	No	No	No	No	No	Yes	No
RHRU-E	Yes	No	No	No	No	No	No	No	Yes	Yes	No
RHRU-O	Site transports samples to laboratory which is able to do all listed assays and is experienced in providing trial testing.										
RHRU-S	Site transports samples to laboratory which is able to do all listed assays and is experienced in providing trial testing.										
RHRU-Y[5]	Yes	No	No	No	No	No	No	No	Yes	Yes	No
RK KHAN	Yes	No	No	No	No	No	No	No	No	Yes	No
SRC	Yes	No	No	No	No	No	No	No	No	Yes	No
THAI	No	No	No	No data provided	No data provided	No data provided	No data provided	No data provided	No data provided	Yes	No data provided
UAB	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Site	HIV rapid tests	HIV RNA PCR	HIV serology	Hema-tology: CBC	Renal function tests[1]	Liver function tests[2]	CD4+ testing	Viral load testing	STI testing	Urine pregnancy testing	Hepatitis B assay
UN	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
UNC	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
UPENN	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
UPITT	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
UPR	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
USF	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
UTH	Yes	No	Yes	No	No	No	No	No	Yes	Yes	Yes
UVRI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
UZ/UCSF	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
YRG	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

[1] Renal functions tests include creatinine, urea, and serum electrolytes.
[2] Liver function tests include alkaline phosphatase, ALT, AST, and total bilirubin.
[3] Studies generally require a central lab for safety, viral load, CD4+ and special immunology. The site has trained and certified lab technicians who ship to a variety of labs, depending on the study requirements. For routine CBC, chemistries, CD4+, viral load, hepatitis, and STI testing, ARCA uses the local Quest lab. ARCA uses Blood Centers of the Pacific for detuned HIV assays.
[4] Beginning Winter/Spring 2008
[5] State of the art laboratory exists with 3 km of the RHRU-Y site.

Table 8: Laboratory Capacity: Storage and Procedures

Site	Storage facilities	GLP-compliant procedures	QA/QC program
ARCA	Two -70°C freezers with temperature control and alarms and one 20°C refrigerator available on site	Yes	CLIA certification
BLHC	No data provided	No data provided	No data provided
BPCRS	-40°C deep freezer which is monitored by means of daily temperature logs. Samples are centrifuged and packed in storage boxes. Details pertaining to the sample are documented on the logs which were provided to the site.	Yes: labs are referred to local lab	Labs are accredited
CAPRISA	Specimens collected by clinical staff who have undergone protocol-specific training and who follow SOPs. Specimens transported from site twice daily to the associated laboratory with processing delay of no more than 4 hours. Transport and handling systems for sites have been established and tested for reliability. Tracking of specimens is maintained by documenting each handling step, which ensures chain of custody. CAPRISA lab has devised LRFs and Shipping Manifests to record number and type of specimens, time and date, and signature of the person who collected the specimens. Specimens are collected according to the Schedule of Events and/or Specimen Procurement Table(s). To ensure that the correct specimens are collected for the correct visit, pre-packed specimen kits are prepared which contain copies of the LRFs and the required number of collection tubes, slides, swabs and containers. When specimens are ready to be shipped, each packet's details (patient ID number, specimens, date and time) are registered on a Shipping Manifest and the courier contacted. Time of collection and courier's signature are recorded on the Manifest, and time and signature of the person receiving the specimens in the laboratory. To monitor the "cool chain" from field site to the lab, temperature monitors will be placed in the specimen cooler boxes. In the laboratory the integrity, type and quantity of the specimens are checked and verified (according to study specific Schedules of Evaluations). Specimens are sorted for local processing and storage or onward-shipping. Aliquoted samples for storage are recorded on sample storage grids which are filed indefinitely. All refrigerators and freezers are monitored to ensure appropriate storage conditions.	Yes	Laboratory has a QA program in place ensuring the maintenance of recommended conditions for pre-analytical, analytical and post-analytical processes. Generation of quality results is achieved daily quality control procedures and subscription to external quality assurance programs allowing for peer review. The CAPRISA Research Laboratory is SANAS accredited and participates in EQA or Proficiency Testing programs such as UKNEQAS and VQA.

Site	Storage facilities	GLP-compliant procedures	QA/QC program
CIDRZ	At least 3 Revco -80°C freezers	Yes	UKNEQAS; CAP
DTHF	Not available	Yes: labs are referred to local lab	Labs are accredited
EC	Not on site – would be sent to a central lab	Yes	Currently underway
FEE	Two -70°C freezers and two -20°C freezers	Yes	Internal controls and external control with CAP
ICRH	Two -80°C freezers are available on site and a third is being ordered. Liquid nitrogen storage facilities available.	Yes	Various EQA programs in place for HIV testing, diagnostic HIV PCR, hematology, biochemistry and CD4+ count through UKNEQAS, BARC SA, ITM Antwerp.
INMENSA	Complete capacity to store samples in -70°C and liquid nitrogen environment	Yes	CAP, UKNEQAS, VQA
ISIP	Refrigerator and freezers are available on site for storage on a small scale. Infrastructure is available on site for more equipment to be housed. Serum and plasma stored at 2-8ºC after collection, cytobrush samples stored at 2-30ºC, and PBMCs stored at -70ºC.	Yes	As part of HPRU In-house lab QA/QC Programme, + and – controls are tested weekly, for rapid test kits when there's a change in lot number for pregnancy and HIV test kits. Reagents, eye wash, and RSID for human semen test assessments done on a monthly basis or for every new lot number. Wet mount reproducibility tests done once every week. pH strips tested monthly and for every new lot number. Unit also has random wet mount proficiency testing of all medical technologists to ensure consistency and accuracy in reporting. Out-sourced lab used for Phase 3 trial sent blinded samples for analysis of proficiency for assessment of *T. vaginalis* on each quarter.
IST	Several -20ºC freezers and one -80ºC freezer	Yes	During trials, participate in QA/QC program set up by trial. At all times, participate in QC program of the STI Diagnostic initiative at WHO for *N. gonorrhoeae* and *C. trachomatis* NAAT testing
KCMC	Storage capacity is -180ºC, -80ºC, -20ºC, and +4ºC	Yes	CAP, NHILS
KEMRI	-80ºC and -20°C freezers and liquid nitrogen storage available	Yes	Through CLS
LSHM	Sponsor provided -20°C local temporary freezers until being shipped to sponsor for storage at -80°C	Yes	Through the CDC and External quality control of CRESAC
MCR	-40°C freezer	Yes: labs are referred to local lab	Labs are accredited
MDP MAW	-20°C and -80°C freezers for storage of specimens	Yes	Several QA/QC programs, including CDC/WHO for syphilis serology, CLS South Africa for HIV, NHS South Africa for HSV, QMCD for CT/NG, and RCPA for urine pregnancy
MIRIAM	Lab has been approved by HPTN, HVTN, ACTG	Yes	NIH-mandated

Site	Storage facilities	GLP-compliant procedures	QA/QC program
MRC DUR	CLS in Johannesburg	Yes: labs are referred to local lab	Internal & external QA/QC process, depending on tests
MRC HLA	Centralized facility for specimen archive at 491 Ridge Road in Overport, Durban. Site enters specimens onto LDMS, stores temporarily and ships once weekly to Durban with shipping disks. Specimens are received, disks imported onto LDMS and specimens archived at Ridge Road.	Yes	CAP proficiency testing, internal quality control panels
MUDHOL	-20°C deep freezers and refrigerators at both sites	Yes	In collaboration with ITM Antwerp
MUMS	PBMC and cytobrush cell samples not available on site but available in collaborating labs	Yes	Yes
NARI	No data provided	Yes	No data provided
PHIVA	-40°C freezer	Yes: labs are referred to local lab	Labs are accredited
PU	-40°C deep freezer and a -80°C freezer	Unknown	Checklist in place for all testing done. All tests reviewed by another person, either the laboratory manager or the site manager.
QECH	No data provided	Yes	No data provided
QM	-40°C freezer	Yes: labs are referred to local lab	Done by local laboratory. Process not available. Laboratory accredited by SANAS.
RHRU-E	-40°C freezer	Yes: labs are referred to local lab	Labs are accredited
RHRU-O	Site transports samples to laboratory which is able to do all assays listed in Table 7 and is experienced in providing trial testing.		
RHRU-S	Site transports samples to laboratory which is able to do all assays listed in Table 7 and is experienced in providing trial testing.		
RHRU-Y	The site lab is CLS, 5 minutes away. It has the capacity to conduct all assays listed in Table 7 and has appropriate storage facilities.	Yes: labs are referred to local lab	They can provide the site with samples for testing. QA/QC programs are offered by the support lab for tests completed on the site.
RK KHAN	Centralized facility for specimen archive at 491 Ridge Rd. Site ships specimens which are entered in LDMS and archived at Ridge Rd.	Yes	Yes
SRC	Stored at room temperature daily and sent via courier to the main lab. For interim periods, stored at 4-8°C, for longer periods sent to MEDUNSA and stored at -20/-70°C.	Yes	Main lab involved in QA program and assessed on-site lab depending on protocol requirements. Blinded specimens from main lab were sent to on-site lab for testing.
THAI	Refrigerator	No	No data provided
UAB	Specimen repository located in basement of Community Care Building (2,250 sq.ft. with specimen processing area, specimen control tracking (computer) center, and freezer	Yes	CLIA and CAP

Site	Storage facilities	GLP-compliant procedures	QA/QC program
	room with twelve -70°C freezers, four liquid nitrogen freezers, and two -150°C freezers. Repository has provided processing, storing, and/or storing services for nearly 60,000 blood and tissue specimens from 2002-07.		
UN	-80 °C freezers which can store 50,000 specimens	Yes	Guided by national guidelines
UNC	Site has -20°C and -70°C freezers for sera and plasma storage and a liquid nitrogen facility for PBMC cell samples	Yes	UKNEQAS, CAP
UPENN	-20°C and -70°C freezers with alarms	Yes	Yes
UPITT	MTN Central Lab	Yes	Yes
UPR	No data provided	Yes	No data provided
USF	The CRI-IDL facility has -20°C and -80°C freezers for sera and plasma, and a liquid nitrogen freezer for storage of PBMCs. All storage system temperatures are electronically monitored 24 hours/day. Specimens are processed on-site and registered into LDMS. Staff is IATA certified for shipment of hazardous goods	Yes	Follows an internal QA/QC plan utilizing NIH-NIAID-DAIDS/GCLP guidelines. CLIA/CAP/State of FA certification/licensing to perform clinical flow cytometry (CD4+/CD8+) testing is pending.
UTH	Serum is stored in a -20°C; Buffy Coat is stored in -70˚C	Yes	The lab has a QA/QC program with NHLS and CLS both of South Africa and it has an internal QA/QC program with CIDRZ lab in Lusaka.
UVRI	Cryogenic storage, consisting of several cryo tanks with capacity to store up to 7,000 samples. The laboratory has a back-up liquid nitrogen tank at the site and there is back-up power and 24-hour monitoring of all equipment.	Yes	UKNEQAS, NHLS, VQA and QASI
UZ/UCSF	Serum and plasma stored at -80°C. PMBC stored in liquid nitrogen. Not storing cytobrush samples currently. Central laboratory with -20 °C and -80°C freezers, temperature-monitored twice daily, with back-up generators.	Yes	CAP, VQA, UKNEQAS and ZINQAP
YRG	Laboratory is equipped with deep freezers and walk in cooler room. These are supported by back up power and dedicated software for samples' handling and protection.	Yes	Lab is certified by most premier international certifying agencies including CAP. Lab has a dedicated highly-qualified team that develops SOPs for each protocol. Annual training program for all staff and skills review is part of employee assessment process.

Table 9: Data Management

Site	USFDA/EMEA compliant data management procedures	Record maintenance program for source documents	SOPs for case report forms	Data management software
ARCA	Yes	Yes	Yes	Clinical trial CRFs are generally paper; different sponsors use different software; site database is in MS Access; site capable of electronic data management through various software systems, including InForm.
BLHC	Yes	Yes	Yes	SCHARP responsible for analysis.
BPCRS	Evaluated to be compliant with the relevant parts of 21 CFR Part 11, ICH GCPs, and applicable guidelines	Yes	No	DF/Net
CAPRISA	Yes (Compliant with 21CFR part 11)	Yes	Yes	CAPRISA has full DataFax capability and all CAPRISA study data are managed locally with DataFax.
CIDRZ	Yes	Yes	Yes	Site is part of MTN, and has DataFax with SCHARP responsible for analysis; or site capable of electronic data management through various software systems
DTHF	Yes	Yes	Yes	None
EC	Yes	Yes	Yes	DataFax
FEE	Yes	Yes	Yes	DF/Net Research
ICRH	No	No	No	Databases are built with MS Access and EpiData depending on study; STATA and SPSS for data analysis.
INMENSA	Yes	Yes	Yes	Commercial (SPSS, Stata, Epi Info) and homemade (SISQUAL) software
ISIP	Yes	Yes	Yes	Population Council Barcode System; MS Excel and Word; Population Council Access Database
IST	Yes	Yes	Yes	MS Access (also used software proposed by FHI, including remote data entry, during the CS trial, with no problems)
KCMC	Compliant with the relevant parts of 21 CFR Part 11, ICH GCPs and applicable guidelines	Yes	Yes	DF/Net, LDMS, MS Access
KEMRI	Yes	Yes	Yes	DataFax
LSHM	Yes	Yes	Yes	MS Access and SAS
MCR	Evaluated to be compliant with the relevant parts of 21 CFR Part 11, ICH GCPs, and applicable guidelines	Yes	Yes	DF/Net
MDP MAW	Procedures are not compliant	Yes, source	Yes	Bespoke system designed by CTU, based on SQL-server and Access.

Site	USFDA/EMEA compliant data management procedures	Record maintenance program for source documents	SOPs for case report forms	Data management software
	with FDA requirements. Site is mostly compliant with EMEA, although data management system (MDP database) has never been validated	documents are stored in locked filing cabinets		It is mostly compliant with GCP requirements, however, it has not been validated.
MIRIAM	Yes	Yes	Yes	Depends on the network, most data goes via DataFax to SCHARP.
MRC DUR	Evaluated to be compliant with the relevant parts of 21 CFR Part 11, ICH GCPs, and applicable guidelines	Yes	Yes	DF/Net
MRC HLA	Yes	Yes	Yes	Data faxed to SCHARP.
MUDHOL	Yes	Yes	Yes	SQL
MUMS	Yes	Yes	Yes	Citrix software
NARI	Yes	Yes	Yes	No data provided
PHIVA	Evaluated to be compliant with the relevant parts of 21 CFR Part 11, ICH GCPs, and applicable guidelines	Yes	Yes	DF/Net
PU	No data provided	Yes	No data provided	No data provided
QECH	Yes	Yes	Yes	Full capacity for DataFax, STATA, E data, EpiData
QM	Evaluated to be compliant with the relevant parts of 21 CFR Part 11, ICH GCPs, and applicable guidelines	Yes	No	DF/Net
RHRU-E	Evaluated to be compliant with the relevant parts of 21 CFR Part 11, ICH GCPs, and applicable guidelines	Yes	Yes	DF/Net
RHRU-O	No data provided	Yes	Yes	At present an SQL database with MS Access front end, on-site manual data entry and cleaning; site has experience in DataFax.
RHRU-S	No data provided	Yes	Yes	At present an SQL database with MS Access front end, on-site manual data entry and cleaning; site has experience in DataFax.
RHRU-Y	Evaluated to be compliant with the relevant parts of 21 CFR Part 11, ICH GCPs, and applicable guidelines	Yes	Yes	MS Access on site but also have access to data managers who use STATA and SPSS. The RHRU has an internal data management centre at CH Baragwanath Hospital which is able to do manual or other forms of data entry and data management and analysis. The site has experience with online data entry and DataFax.

Site	USFDA/EMEA compliant data management procedures	Record maintenance program for source documents	SOPs for case report forms	Data management software
RK KHAN	Yes	Yes	Yes	Data faxed to SCHARP
SRC	Yes	Yes	Yes	DataFax
THAI	Yes	Yes	Yes	MS Access, SAS
UAB	Yes	Yes	Yes	Site is part of MTN, and all study related data is managed by SCHARP. The other networks also have data coordinating centers.
UN	In development			
UNC	Yes	Yes	Yes	MS Access and Excel
UPENN	Yes	Yes	Yes	DataFax, also part of HVTN
UPITT	Yes	Yes	Yes	No data provided
UPR	Yes	Yes	Yes	No data provided
USF	Yes	Yes	Yes	No data provided
UTH	Yes	Yes	Yes	MDP 301 trial database (consists of a SQL server database and a front-end application written in MS Access 2000)
UVRI	Yes	Yes	Yes	MS Access, Excel, Word
UZ/UCSF	Yes	Yes	Yes	Most trials have used DataFax. Some studies are manually entering hard copy forms into customized, Access-based databases. Some studies are using Web-based electronic data entry system (ie. ACTG and PACTG trials).
YRG	Yes	Yes	Yes	Data management team developed Oracle- and MS Access-based data systems. A dedicated records management unit secures all research documents. A detailed and multi-level secured process ensures minimal and need-to-know access only to these documents. Detailed SOPs available on site.

Table 10: Funding, Collaborations, and Institutional Review

Site	Principal sources of funding	Significant collaborations	Established in-country review/approval process	Character of site location	PEPFAR support for ARV program
ARCA	Diversified funding includes pharmaceutical /biotech, CDC, NIH, State of GA, donations	Universities (Georgia State University, University of Georgia, Spelman College, Morehouse College, and University of Colorado); public health departments (primarily Fulton, DeKalb, Cobb, and Douglas Counties); multiple AIDS service organizations (AID Atlanta, AIDS Survival Project, Our Common Welfare, SisterLove, National AIDS Education and Services for Minorities), and local non-profit organizations (YouthPride, Center for Black Women's Wellness)	ARCA has its own IRB that meets monthly. Timeliness of regulatory review does not present a barrier.	Community-based	N/A
BLHC	NIH	None	Yes	Hospital-based	No
BPCRS	IPM	None	Central REC: Pharma Ethics; National Health REC Registration; National Regulatory Authority: MCC	Community-based	N/A
CAPRISA	NIH and USAID	CAPRISA is a multi-institutional organization and collaborates with local, national and international researchers. The five major partner institutions in CAPRISA include: University of KwaZulu-Natal, University of Cape Town, University of Western Cape, National Institute for Communicable Diseases, and Columbia University. CAPRISA is closely linked with the Columbia University-Southern African Fogarty AIDS International Training and Research Program. There is a long standing collaborative relationship between senior AIDS and tuberculosis researchers from Columbia University and Harvard University with their counterparts at the University of KwaZulu-Natal in South Africa. Other significant collaborations include the local DOHs, Aurum Health, WHO, UNAIDS, CONRAD, LifeLab and FHI.	University of KwaZulu-Natal's BREC, located at the Nelson R Mandela School of Medicine - FWA #: 00000678. All research INDs or testing a new indication of a licensed product needs approval from the MCC.	Community-based	Yes, also partially funded by the Global Fund. AIDS care also provided in terms of an MOU with the South African DOH

Site	Principal sources of funding	Significant collaborations	Established in-country review/approval process	Character of site location	PEPFAR support for ARV program
CIDRZ	NIH CTU MTN CRS	Zambian MOH; University of Alabama at Birmingham; University of Zambia – University Teaching Hospital; CDC; World Food Programme	University of Zambia School of Medicine REC; Zambian national REC; Pharmacy Regulatory Authority	Community-based	Yes
DTHF	IPM for specific study; but DTHF is widely funded for various research projects, e.g. NIH	City of Cape Town (local government), Provincial DOH, University of Cape Town	Institutional REC: UCT Research Ethics Committee; National Health REC Registration; National Regulatory Authority: MCC	Community-based	No
EC	PC, FHI, MTN	Setshaba Research Centre, University of Limpopo, South Africa, South African MRC University of the Western Cape, South Africa, University of Washington, Seattle, USA	University of Cape Town Ethics Committee, Provincial Department of Health Ethics Committee, MCC of South Africa, National Ethics Committee	Community-based	No
FEE	US NIH/US NIAID	None	Local Bioethical Committee Review and National Direction of Health of MOH	Community-based	No
ICRH	EC, ANRS, USAID, WHO, IPM	WHO, Ghent University, University of Nairobi	An established national ethical research committee is in place. The Pharmacy and Poisons Board's Expert Committee on Clinical Trials.	Hospital-based; community-based; university-based	Yes
INMENSA	Mainly US NIH	MOH of Peru; Bristol Myers Squibb; Merck & Co; Schering Plough Research Institutes, PPD Pharmaceuticals	NIH at the MOH of Peru approves and regulates the conduct of clinical trials in the country. After obtaining local IRB approval (1-2 months), a complete application packet containing IRB approval letter, study drug investigator's brochure, investigator's CV, specific study drug information (e.g., stability studies, certificate of analysis, GMP certificate and study drug and lab importation list) is sent for NIH review. NIH approval process (2-3 months). Additional paperwork (1 week) should be conducted at Peruvian customs for importation clearance purposes. After approval, regular NIH auditing visits are conducted until study finishes.	Community-based; NGO	No

Site	Principal sources of funding	Significant collaborations	Established in-country review/approval process	Character of site location	PEPFAR support for ARV program
ISIP	Phase 3 Carraguard trial: USAID and Gates Foundation via the PC. Referrals and ACASI sub studies also funded by PC. Site has been through an assessment visit for consideration as a future vaccine trial site by the HVTN.	Site partners with the University of Kwazulu Natal, HIV Pathogenesis Programme, Acute Infection Study for monitoring of seroconverters. There is no financial benefit to the site from this collaboration aside from accessing free monitoring of seroconverters. Within the HIV Prevention Unit, there was collaboration between the SPARTAC study and the Phase 3 Carraguard study (seroconverters were given the option to screen for enrollment). MOUs have been initiated and a Referral Network of Care identified with local ARV rollouts, public hospitals and local service providers, NGOs and community based organizations within the study's recruitment area to support and provide ongoing care for trial participants as required during and after trial/study closure.	Nationally, the University of Kwazulu Natal BREC committee reviews and approves all protocols, informed consents and amendments prior to implementation at the study sites. BREC is updated of any SAEs, pregnancies and seroconversions as they occur. DSMB meeting minutes/reports are submitted to the local IRB for review. Any research based study at the MRC is approved by a full committee of the BREC prior to implementation. The MCC of South Africa has to approve any IND to be brought into the country. Studies may not commence without MCC approval.	Community-based	Yes: PEPFAR supports the HPRU Clinics at Carlisle Street in Central Durban and in Verulem. However, the National ARV rollouts at two provincial hospitals are where most trial participants are referred (MOUs have been established with them).
IST	Different research and capacity building projects held by the CHA, with basic funding for STI preventive and clinical services to FSWs from Benin's MOH	Benin MOH; Faculty of Health Sciences, University of Abomey-Calavi, Benin; National University Hospital Centre; various local NGOs	Process is ad hoc, but, with the support of one of capacity building projects, should be a permanent national ethics committee set up in 2008.	Hospital-based; community-based	No (support provided by Global Fund through National AIDS Program)
KCMC	IPM	None	Harvard School of Public Health; Kilimanjaro Christian Medical College; National Institute for Medical Research; The United Republic of Tanzania Ministry of Health & Social Welfare	Community-based	No data provided
KEMRI	NIH, Gates Foundation, CDC-PEPFAR	UCSF, University of Washington	KEMRI Ethical Review Committee	Community-based; Other	Yes

Site	Principal sources of funding	Significant collaborations	Established in-country review/approval process	Character of site location	PEPFAR support for ARV program
LSHM	Trial sponsor, CDC, Cameroon Government	NIH, CDC, University of Washington, Seattle	Cameroon MOPH and Cameroon National Ethics Committee must approve clinical trials before start	Community-based	Support provided by global funds
MCR	IPM	No	Central Research Ethics Committee: Pharma Ethics; National Health Research Ethics Committee Registration; National Regulatory Authority: MCC; District Regional approval	Community-based	N/A
MDP MAW	DFID funding through MRC	LSHTM; AMREF lake zone project, Mwanza, Tanzania; NIMR, Mwanza, Tanzania	Approval required prior to study start and for every protocol amendment by: Tanzanian MRCC Ethics sub committee, TFDA, LSHTM Ethics Committee. Six monthly study updates (including SAE listings) sent to NIMR Dar es Salaam/Mwanza; MRCC Ethics sub committee; TFDA; AMREF, Mwanza, Dar es Salaam; LSHTM Ethic Committee. Expedited SAEs sent real time to MRCC Ethics sub committee, TFDA, LSHTM Ethic Committee.	Clinical site based in mobile clinics but research coordinating center based at LSHTM/ NIMR/ AMREF collaboration in Mwanza (University, Research Institute, and NGO, respectively)	Yes
MIRIAM	NIH	Industry (e.g. Gilead)	Yes	Hospital-based	No
MRC DUR	IPM for specific study, but MRC is widely funded for various research projects	None	University of KwaZulu Natal	Community-based	No
MRC HLA	NIH grant	DOH: Hlabisa Hospital (VCT, rape crisis centre, family planning, antenatal/perinatal); Social Welfare (psychologist/counseling and disability, child support, and foster care grants); Dept of Agriculture (vegetable gardens in community for sale/consumption);	MCC approves all protocols for drugs/intervention studies: initial submissions, all investigators and new investigators, six monthly progress reports. BREC approves all protocols: initial submissions, continuous review	MRC clinic consisting of prefabricated buildings placed on MRC land in	No

Site	Principal sources of funding	Significant collaborations	Established in-country review/approval process	Character of site location	PEPFAR support for ARV program
		Hlabisa Municipality (financial support if a group wanted to form an income generating project); Umyezi (home-based care, will start project to look after orphans, working with lovelife educators); Vusimpilo (home-based care, HIV awareness); Malusi Omuhle Aids Project (home-based care – giving tablets and food parcels, start project to look after orphans in 2004); Gateway Clinic-Hlabisa Hospigate (same as Hlabisa hospital but refers to hospital); Hlabisa SAPS (rape, domestic violence, refers to the Crisis Centre); Sibambisene (new at Hlabisa, operates in the whole of Umkhanyakude district, will be an umbrella body for all NGOs and CBO in Hlabisa)	(annually), all investigators, all SAE reports and all protocol violations	the Hlabisa ward of the Hlabisa district	
MUDHOL	CONRAD; prime recipient of the grant was the University of Manitoba, Winnipeg, Canada. St John's Medical College and Karnataka Health Promotion Trust implemented the trial.	Bagalkot district was an "HIV Prevention Rural Demonstration Project" under the India-Canada Collaborative HIV/AIDS Project, funded by CIDA from 2001-06. It is one of the districts included under the "Corridors" focused HIV prevention project and the migration research project; funded by the Avahan; the Gates Foundation India-AIDS-Initiative. (2005-08). It is currently a rural demonstration-learning site for the HIV prevention and care Samastha project, funded by USAID (2006-11). All of these projects were implemented through the University of Manitoba, KHPT and St John's.	Ethical approval is sought from an institution that is affiliated to ICMR. In most instances, this approval is sufficient for research. For all externally funded projects, need clearance from the Health Ministry Screening Committee that is set up as an independent body within the ICMR. Clearance from this committee and the ICMR is mandatory. For trials of products or drugs, clearance is required from the Drugs Controller General India, New Delhi. For export of biological samples for quality control or other testing, further approval is required from the Directorate General of Foreign Trade. Procedures are fairly well-defined and take 6-12 months for complete approval. CROs are also available to facilitate the process.	Hospital-based; community-based; university-based	No
MUMS	None currently; site was set up by CONRAD for cellulose sulfate study	MOH, Mulago Hospital, Infectious Disease Institute, AIDS support organization	Reviews are through the AIDS Research Committee of the Uganda National Council for Science and Technology	Hospital-based; university-based	Yes

Site	Principal sources of funding	Significant collaborations	Established in-country review/approval process	Character of site location	PEPFAR support for ARV program
NARI	No data provided	No data provided	No data provided	No data provided	No data provided
PHIVA	IPM	None	Central REC: Pharma Ethics; National Health REC Registration; National Regulatory Authority: MCC	Community-based	Yes
PU	IPM	National Reference Laboratory ; AMC-CPCD; Treatment and Research for AIDS Center; Columbia University	Rwanda National Ethics Committee; Columbia University IRB, as applicable	Community-based	No data provided
QECH	No data provided	MOH and Johns Hopkins School of Public Health	In-country review process by COMREC	No data provided	No data provided
QM	IPM	None	Central REC: Pharma Ethics; National Health REC Registration; National Regulatory Authority: MCC	Community-based	No
RHRU-E	IPM for specific research center, but RHRU is also funded from various other sources	Yes	Wits Ethics	Community-based	Yes
RHRU-O	MDP through MRC CTU grant from DFID	Imperial College London, MRC CTU London, University of North Carolina and Duke University, LSHTM, IPM	Site has access to the University of the Witwatersrand Human REC, a National Ethics Committee and the MCC	Community-based	Yes
RHRU-S	MDP through MRC CTU grant from DFID	Imperial College London, MRC CTU London, University of North Carolina and Duke University, LSHTM, IPM	Site has access to the University of the Witwatersrand Human REC, a National Ethics Committee and the MCC	Community-based	Yes
RHRU-Y	Primarily IPM funded studies, but also studies funded by CONRAD. The RHRU has sites that are funded by a wide range of donors including NIH, DFID,	Imperial College London, MDP with MRC CTU London, LSHTM, University of North Carolina and Duke University amongst others.	Institutional REC: Wits Human REC; National Health REC Registration; National Regulatory Authority: MCC	Community-based	Yes

Site	Principal sources of funding	Significant collaborations	Established in-country review/approval process	Character of site location	PEPFAR support for ARV program
	European Union and others.				
RK KHAN	NIH grant	DOH (local, provincial, national), CBOs, NGOs: Havenside Civic Association, Havenside Womens Activity Group, Hope for Children, Hope Development Forum, Kannama Community Crisis Care Center, ART-Association for Retired Teachers, Ray of Hope, Kharwastan Senior Citizens, Mobeni Heights Civic Association, Montford Senior Citizens, Montford Womens Activity, Moorton Community Development Forum, Moorton Womens Group, Operation Reach Out, Parents Association of KZN, Welbedacht Community Care Center, Welbedacht Compassion Center, Woodhurst Civic Association, Umhlatuzana Civic Association, Chatsworth Pensioner's Forum, Sarva Dharma Ashram, Saiva Sithatha Khazagum, Sathya Sai Sarva Organisation, Chatsworth Umbrella Body, Club 91, Chatsworth Policing Forum and Chatsworth SAPS. For additional information and contact persons for each organization, contact RK KHAN.	The MCC approves all protocols for drugs /intervention studies—initial submissions, all investigators and new investigators, six monthly progress reports. The BREC approves all protocols–initial submissions, continuous review (annually), all investigators, all SAE reports and all protocol violations.	MRC clinics consist of pre-fabricated buildings in the parking lot of PHC clinic in the grounds of R.K. Khan Hospital in Chatsworth	No
SRC	USAID; Gates Foundation	None	MCC and University of Limpopo-Medunsa Campus Ethics Committee	Community-based; university-based	No
THAI	CDC/DHAP	Thailand MOPH, Bangkok Metropolitan Administration	University, Governmental Ethical Committees	Hospital-based, community-based	No
UAB	NIH/DAIDS	MTN, HVTN, and Adult Treatment Trials Networks	N/A (UAB IRB reviews protocols in which UAB investigators participate)	University-based	N/A
UN	FHI through NIH	Multicenter study: Kenya (2 sites), Tanzania, South Africa and Malawi	Yes	University-based; community-based	No data provided

Site	Principal sources of funding	Significant collaborations	Established in-country review/approval process	Character of site location	PEPFAR support for ARV program
UNC	NIH, CDC	MOH Malawi; National AIDS Commission, Malawi; College of Medicine, Malawi; Elizabeth Glaser Pediatric AIDS Foundation	All research proposals need approval from the NHSRC, which meets every other month. Protocols are expected in NHSRC offices two weeks prior to meeting date. NHSRC has a protocol format which they expect all protocols to follow. Exemptions may be made for multi site/national protocols needing approvals in other countries. UNC project expects all protocols associated with the project to be in project office 4 weeks before NHSRC meeting date to provide ample time for translations etc.	Hospital-based; community-based; university-based	N/A
UPENN	NIH/DAIDS	MTN, HVTN, ATN at CHOP	University of Pennsylvania IRB	University based with a mobile medical assessment unit to recruit, retain and perform study visits in areas of high-risk populations	N/A
UPITT	NIH–DAIDS (Clinical Research Site)	None	University of Pittsburgh	University-based	No
UPR	No data provided	No data provided	No data provided	No data provided	N/A
USF	No data provided	ATN, IMPAACT	University of South Florida	University-based	N/A
UTH	DFID through MRC CTU, UK	University of Zambia, University Teaching Hospital	1. University of Zambia REC 2. Pharmaceutical Regulatory Authority	Community-based	Yes[1]
UVRI	MRC (UK), DFID	MRC Clinical Trials Unit, London; LSHTM; Imperial College, London; Indevus Pharmaceuticals, Lexington; IAVI; Wellcome Trust, London; WHO	The local IRB is the UVRI Science and Ethics Committee that reviews all study protocols. Upon approval, submission is then made to the National IRB (Uganda National Council of Science and Technology).	Research institution	No data provided
UZ/UCSF	NIH (as CTU for MTN,	Sites are a collaboration between UCSF and the University of Zimbabwe, College of Health	The MRC of Zimbabwe approves research carried out in public and	Hospital-based;	No

Site	Principal sources of funding	Significant collaborations	Established in-country review/approval process	Character of site location	PEPFAR support for ARV program
	ACTG, HPTN and IMPAACT)	Sciences (Departments of Obstetrics and Gynaecology, Medicine, Paediatrics, and Community Medicine. Other collaborations include CONRAD, FHI, and the Gates Foundation.	private institutions and analyses protocols and consent forms before approval. Protocols with investigational drugs or devices must be reviewed by the Medicines Control Authority of Zimbabwe; since there will be INDs under trial, this council will play an important role.	community-based; university-based; primary clinic-based	
YRG	Site is a recipient of NIH funding through HPTN, AACTG and NIMH study sponsorships. Additionally, site receives funding from private donors and foundations. Site is also a recipient of Global Fund funding.	Site works with IAVI and the government of India on HIV preventive vaccine trials; with ICMR on a Phase 3 microbicide trial; and with UNICEF and UNDP on developing appropriate training materials for schools and police personnel. Currently the site is working with IAVI and PC to look at feasibility of involving MSM in clinical trials, specifically HIV preventive vaccines.	YRGCARE has an ethics committee (IRB) and a CAB to oversee the conduct of trials and studies, including adverse events and annual reviews apart from routine protocol review. All implementation is subject to IRB and CAB approvals at the first level. After this process, documents are submitted to the ICMR for expert panel review. Once this process is completed, documents are sent to an apex body (Health Ministry Screening Committee) for final approval. If drugs or devices are involved that need to be imported, additional clearance from the Drug Controller General of India is mandatory. If there is a requirement for samples' export, a material transfer agreement with Government of India's Department of Biotechnology is required.	Hospital-based; community-based	No

[1]UTH refers clients needing ARVs to the National ARV program (through the district Hospital) which is heavily supported by the Global Fund (PEPFAR).

Table 11: Critical Modifications Needed and Additional Comments

Site	Modifications needed to strengthen site for optimal implementation of clinical trials	Additional Comments
ARCA	ARCA is fully capable of designing and implementing clinical trials without significant modifications. For microbicide trials, training in sample collection procedures for cervical or rectal microbicides; adequate marketing and outreach resources.	ARCA is eager to continue to be involved in PrEP trials that include men and women. The African-American population in Atlanta is at high risk for HIV and the educational work ARCA has done over the past years has increased acceptability of such trials in this community, which is traditionally difficult to reach. Experience with the CDC US PrEP trial additionally has helped to understand better methods of trial preparation, marketing, and implementation that would yield faster enrollment. Although ARCA has not conducted microbicide trials, the site is quite expert in the conduct of clinical trials and has highly experienced clinical trial staff capable of conducting such trials. ARCA has not participated in a microbicide trial to date only because of the rarity of such opportunities. ARCA has an excellent staff, longstanding relationships with communities at risk for and with HIV infection, and 20 years of experience in the design and conduct of clinical trials.
BLHC	More financial resources for recruitment (e.g. advertising funds) in order to recruit appropriate participants quickly.	No data provided
BPCRS	More clinical trials to build knowledge and develop staff in the field of research.	No data provided
CAPRISA	Improved reliability of electricity supply; improved public transport so that staff can get to work reliably.	No data provided
CIDRZ	More physical space for clinic and lab; more GCLP training for lab staff; more CAB and community development; dedicated research pharmacist.	Strong history of Satanism beliefs in the community regarding blood draw and specimen collection, but this is lessening as more studies are conducted in this community. Engage with REC. Site has proven track record and ability to ensure a clinical trial can be carried out successfully.
DTHF	Additional clinical space to be built; comprehensive educational/awareness program around microbicides.	Engage actively with the community to educate on microbicide science and research; Engage with REC.
EC	Development of a pharmacy	No data provided
FEE	Expanding lab's capacity; improving site's infrastructure.	No data provided
ICRH	Data management and archiving facilities and procedures; retention of trained and qualified staff; increased internet access; improved clinical infrastructure; further development of organizational systems and SOPs.	No data provided
INMENSA	Increase site capacity; increase access to women from general population.	None
ISIP	Fully equipped laboratory to do on-site testing (e.g., HIV ELISA, STI testing PCR, CD4+ viral loads) would minimize costs by removal of outsourcing work and decrease turnaround times. Improved/larger budget to accommodate more contraceptive methods apart from condoms. More capacity training for study	Site has proven track record and ability to ensure a clinical trial can be carried out successfully. Effective and open communication with the community network that exists, a community that is keen on participation in clinical research,

Site	Modifications needed to strengthen site for optimal implementation of clinical trials	Additional Comments
	staff. Sufficient funding to purchase the study site to minimize rental costs.	the existing site infrastructure, and highly-skilled GCP, GCLP and enthusiastic clinical trial trained staff make the site an ideal option for consideration for any future clinical trials.
IST	Have infrastructure funding to maintain permanent staff; establish a permanent cohort of FSWs to facilitate recruitment into trials.	For now, projects have to fund a part of the infrastructure costs.
KCMC	No data provided	No data provided
KEMRI	Develop on-site testing for STIs; stable sources of funding to ensure that the site can maintain critical staff positions between studies.	No data provided
LSHM	Space available and lab facilities. Well-trained personnel on site but more financial resources needed.	Site has proven track record and ability to ensure a clinical trial can be carried out successfully. Enthusiastic clinical trial trained staff make the site an ideal option for consideration for any future study.
MCR	Appointment of full-time investigator, full-time pharmacist, and part-time counselor (e.g. for debriefing staff who have to break bad news); equipped laboratory.	No data provided
MDP MAW	Greater incentive for recruiting and maintaining trained senior staff (increased opportunities for growth and training and competitive salary scales). Development of local ethics committee (nationally recognized) to minimize delays in obtaining ethical approvals. Improved internet support and access to enable better daily work efficiency as well as to facilitate literature reviews for scientific writing and continued professional development. Improved logistics for shipping of supplies and stock control (including staff training). Development of greater internal capacity for GCP and GCLP training.	No data provided
MIRIAM	Site is in good shape to continue to contribute to the HIV prevention agenda.	Great community rapport.
MRC DUR	New generator to include downstairs at Overport clinic.	More staff members; archiving of documents; clinic size for Phase 3 trials
MRC HLA	Site has excellent infrastructure for implementation of clinical trials but maintaining professional staff (medical doctors and pharmacists) is a challenge.	No data provided
MUDHOL	Improvement of laboratory capacity for CD4+ testing and basic clinical monitoring of HIV therapy; on-site provision of ARV therapy; strengthen quality assurance within labs and capacity for internal analysis within the country, rather than depending on external labs and capacities, as the export of data and samples requires approvals which are time consuming. (Site sent out data for analysis. The only samples sent out were for quality assurance. Most other samples were analyzed either on site or in the site's main labs in Bangalore).	Sufficient time to be given for community preparedness and preparation that goes beyond the most at risk populations involved in the trial. Direct support to be provided for participants who screen out of the trial, rather than being restricted to only those enrolled. Comprehensive primary care to be provided for all those who participate in screening and enrollment, and should not be limited to treatment of STIs.
MUMS	Renovation of existing laboratory; equip laboratory with reagents and more equipment; train one more person to support the laboratory; training to build community component with other stakeholders.	PrEP trials have not started, but collaborating labs are setting up capacity. Site needs to acquire more space and improve communication and transportation.
NARI	No data provided	No data provided
PHIVA	Funding for partition to create separate pharmacy.	No data provided

Site	Modifications needed to strengthen site for optimal implementation of clinical trials	Additional Comments
PU	GCP training; workshops on source documentation, CRFs; lab testing procedures and timelines, especially for tests shipped from the site.	No data provided
QECH	Site has excellent infrastructure for implementation of clinical trials. Maintaining professional staff is a challenge.	No data provided
QM	Enough staff for more trials; financial assistance; GCP compliant; trained staff.	Ability to recruit more professional staff for future studies.
RHRU-E	No data provided	No data provided
RHRU-O	The sites have many experienced clinical trial staff, and excellent clinical trial facilities, however core salary support for senior staff to bridge the time between studies and facilitate the development of independent research and sub studies is difficult.	These are the largest sites in MDP 301. The sites have excellent retention results and have established good community engagement plans and processes. The clinical trial support at RHRU is wider than these sites allowing internal review of process and back up if needed.
RHRU-S		
RHRU-Y	On site generator in the process of being installed; site needs temperature-controlled room to control temperature in “pharmacy room,” additional rooms for a Phase 3 study including dedicated pharmacy, and autoclave for sterilizing of large amounts of patients seen daily in Phase 3.	The RHRU has experience in recruiting participants for Phase 3 trials. This includes 400 women into HPTN 039 and 2,500 in MDP 301. Follow up rates at 1 year are in excess of 85%.
RK KHAN	The site has excellent infrastructure and staff for the implementation of clinical trials. The biggest lack is fully-fledged laboratory to ensure that all the diagnostic testing required for the trials can be performed by MRC-employees – currently most testing is outsourced to a commercial laboratory.	No data provided
SRC	To expand the centre to include multiple satellite sites thereby getting wider coverage. Have more community leaders to foster education promoting increased community awareness and partner involvement in research trials. Increase partnerships with public sector, health department, government, academic institutions and research organizations in partnership with the community, private, public stakeholders and health authorities to work in collaboration to support ongoing clinical trials.	To establish the site under the umbrella body (HVTN) who will by provide support and resources in the promotion of conducting further clinical research to reduce the number of HIV infections.
THAI	No data provided	No data provided
UAB	No data provided	No data provided
UN	Physical facility is scare (would like a complex); capacity building for data management; budget increase; non-research interventions support.	Laboratory being used is registered by UK external quality assurance program; also participating in CDC PCR quality assurance program.
UNC	More space for client activity and storage; more efficient technology for identification of participants enrolled in study (e.g., fingerprint identification to avoid impersonation); GPS technology to improve identification of participant residence; more transport to complement GPS technology.	No data provided
UPENN	Site has infrastructure and staff to successfully conduct Phase 1, 2 and 3 trials.	Site is only US site for HPTN/MTN 035 Phase 2/2B. Has completed three Phase 1 microbicide trials.
UPITT	No data provided	The site will conduct Phase 1 and 2A safety and tolerability studies of potential topical microbial and oral PrEP agents.
UPR	No data provided	No data provided
USF	No data provided	No data provided

Site	Modifications needed to strengthen site for optimal implementation of clinical trials	Additional Comments
UTH	Extension of room space, expansion of lab services	None
UVRI	Regular training for trial staff in relevant fields; backup equipment for critical areas such as the laboratory, data management and other facilities.	No data provided
UZ/UCSF	Laboratory: update equipment, increase number of staff. Additional training and support for laboratory information systems. Expansion of existing/acquisition of more clinical trials units. Upgrading stock management systems and equipment in central pharmacy. Expansion of the existing IT services, upgrade e-mail and telephones. Training and support for core administration. Improve FDA compliant, electronic data capture system.	The sites have been involved in various successful and yet to be completed studies. They have a highly qualified and competent staff compliment. The existing infrastructure, after a few upgrades, will be adequate for further microbicide and/ or PrEP trials.
YRG	No data provided	No data provided

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Appendix B: Trials Conducted at Each Site

ARCA

ARCA has participated in the following research networks/collaborative agreements:

- AmFAR Community Based Clinical Trial Network (1989-1995)
- NIH/NIAID Community Programs for Clinical Research on AIDS (CPCRA): (1989-2004)
- CPCRA/INSIGHT: SMART study of continuous vs. CD4-guided interruption of therapy (2001-2008)
- NIH/CPCRA/INSIGHT: ESPRIT study of Interleukin-2 in the setting of HIV infection (ending 2008)
- Chiron/NIH/INSIGHT: SILCAAT study Interleukin-2 in the setting of HIV infection (2001-ongoing)
- NIH/NIAID: Acute Infection and Early Disease Network (University of Colorado consortium) (2001-2005)
- CDC: Prevention in Medical Care Settings (PICS) Study (2003-2007)
- HRSA: Prevention with Positives Demonstration Projects: (2003-2008)
- CDC: US safety study of tenofovir in HIV-negative MSM (2004-ongoing)
- CDC: Strategies for HIV testing in African-American MSM (2006-ongoing)
- NIH/NIAID Acute Infection R01 Consortium (University of Colorado, Zimbabwe, University of Hawaii, ARCA): (2007-ongoing)

ARCA has conducted over 300 clinical trials since 1988. Most of these are clinical trials of treatments for HIV and its complications. Sponsors include NIH/NIAID, CDC, and over 20 pharmaceutical/biotech companies. A full listing is available on request. ARCA has approximately 15-20 clinical trials ongoing at any given time.

1. **Completed:** CDC: The Adult Spectrum of Disease Study 1989-2004. Sample size: 10,000 patients at ARCA.
2. **Completed:** NIH/NIAID/CPCRA: Observational Database 1989-1994. Sample size: 2,000 patients at ARCA.
3. **Completed:** US Department of Defense/CPCRA: gp160 vaccine in HIV-1 infected persons.
4. **Completed:** Immune Response Corporation: Remune® in HIV-1 infected persons (3 studies).
5. **Completed:** VaxGen: a trial of B/B in HIV-1 uninfected persons (followed 131 persons with only 1 LTFU).
6. **Completed:** CDC: Positive STEPS: An evaluation of the efficacy of brief provider-delivered prevention messages in the medical care setting for persons with HIV. DeKalb and Cobb/Douglas HIV clinics. Sample size: 200 enrolled. Follow-up complete, currently in analysis.
7. **Completed:** HRSA: Project PREVENTS: A comparison of provider-delivered prevention messages alone with provider-delivered prevention messages and prevention specialist visits in an urban HIV clinic. DeKalb County HIV clinic. Sample size: 300 enrolled. Follow-up complete, currently in analysis.
8. **Ongoing:** CDC: The US trial of the safety of tenofovir dipivoxil in HIV-negative men who have sex with men. Sample size: 121 MSM at ARCA. Enrollment complete, follow-up until Dec 2008.
9. **Ongoing:** CDC: Validation of HIV testing with OraQuick Advance® oral swab and fingerstick. Sample size: 350. Estimated completion date: end 2008.
10. **Ongoing:** NIH/University of Colorado: The immunologic and virologic effects of short-term antiretroviral therapy compared with no treatment in the setting of acute and recent HIV infection. Sample size: 10. Estimated completion date: 2009.
11. **Ongoing:** Panacos: Phase 2B trial of beviramat, a first in class maturation inhibitor.
12. **Ongoing:** Progenics: Phase 2B trial of intravenous PRO-140, a monoclonal anti-CCR5 antibody.
13. **Ongoing:** Progenics: Phase 2B trial of subcutaneous PRO-140, a monoclonal anti-CCR5 antibody.
14. **Ongoing:** Theratechnologies: Phase 3 trial of recombinant human growth hormone for HIV lipodystrophy.
15. **Ongoing:** Tibotec: Phase 4 trial of gender race and clinical events (GRACE) with TMC114.
16. **Ongoing:** Tibotec: Phase 3 trial of TMC114.

17. **Ongoing:** Tibotec: Phase 2B trial of TMC278.
18. **Ongoing:** Tibotec: Phase 3 trial of TMC125.
19. **Ongoing:** Merck: Phase 3 trial of raltegravir compared with Kaletra® for patients with viral suppression.
20. **Ongoing:** Koronis: Phase 2B trial of KP-1461, a viral decay accelerator.
21. **Ongoing:** GlaxoSmithKline: Phase 3 trial of atazanavir/ritonavir/Epzicom® induction followed by atazanavir/Epzicom®.
22. **Ongoing:** GlaxoSmithKline: Phase 3 trial of lopinavir/ritonavir with Epzicom® or Truvada®.
23. **Ongoing:** Pfizer: Phase 2B/3 trial of maraviroc in CCR5+ ART naïve patients.
24. **Ongoing:** Pfizer: Phase 2B/3 trial of maraviroc in CCR5+ ART experienced patients.
25. **Ongoing:** Schering-Plough: Phase 3 trial of vicriviroc in CCR5+ ART experienced patients.
26. **Ongoing:** Boehringer-Ingleheim: Phase 3 trial of tipranavir in ART experienced patients.
27. **Ongoing:** NIH: ESPRIT, a trial of SC interleukin-2 in patients with CD4 < 350 cells/µl.
28. **Ongoing:** NIH: SILCAAT, a trial of SC interleukin-2 in patients with CD4 ≥ 350 cells/µl.
29. **Planned:** CDC: Strategies for identifying at-risk African-American men who have sex with men who are unaware of their HIV status. Sample size: 600. Start date: April 08.Estimated completion date: August 31, 2009.
30. **Planned:** Taimed: Phase 3 trial of TNX-355, an anti-CD4 monoclonal antibody.
31. **Planned:** Avexa: Phase 3 trial of apricitibine, a new NRTI.
32. **Planned:** OraSure: HIV home testing with OraSure Advance®.
33. **Planned:** Incyte: Phase 2B trial of a novel CCR5 inhibitor compared with maraviroc in experienced patients.
34. **Planned:** Sponsor confidential: Phase 1 study of a new integrase inhibitor.
35. **Planned:** Sponsor confidential: Phase 2B study of a new integrase inhibitor.

BLHC

1. **Completed**: HPTN 049.
2. **Completed**: HPTN 050.
3. **Ongoing**: HPTN 059.

BPCRS

1. **Ongoing**: IPM100. Sample size: 800 (cross-sectional); 300 (cohort). Estimated completion date: September 2008.
2. **Planned**: IPM015. Sample size: 70. Estimated completion date: 2009.
3. **Planned**: IPM014. Sample size: 40. Estimated completion date: late 2008.

CAPRISA

1. **Completed**: Study of HIV seroincidence among women.
2. **Completed**: The Joint Oxfam HIV/AIDS Programme in South Africa.
3. **Completed**: Understanding HIV/AIDS stigma and discrimination at a community level–perspectives from rural KwaZulu-Natal.
4. **Ongoing**: CAPRISA 004: Phase 2B trial to assess the safety and effectiveness of the vaginal microbicide 1% tenofovir gel for the prevention of HIV infection in women in South Africa. Sample size: 980. Estimated completion date: 2010.
5. **Ongoing**: CAPRISA 104: Microbicide case control study to evaluate behavioral patterns of risk and gel use in a Phase 2B trial. Estimated completion date: 2010.
6. **Ongoing**: HVTN 503 (Merck vaccine trial).
7. **Ongoing**: CAPRISA 001 (TB-HIV Treatment trial).

CIDRZ

1. **Completed**: HPTN 035 Standard of Care Assessment
2. **Completed**: HPTN 055
3. **Ongoing**: HPTN 035
4. **Planned:** Microbicide Legacy
5. **Planned**: MTN 015
6. **Planned**: MTN 003

DTHF

1. **Completed**: Cipra 3A
2. **Completed**: Adolescent Cohort study
3. **Completed**: HIV negative cohort study
4. **Completed**: Tuberculin skin test study (year 1 completed)
5. **Ongoing**: Cipra 1 (ARV treatment)
6. **Ongoing**: Cipra 3B (TB genotyping)
7. **Ongoing**: Tuberculin Skin test study (yr 2)
8. **Planned**: IPM011. Sample size: 20. Estimated completion date: late 2008.
9. **Planned**: IPM015/019. Sample size: 70. Estimated completion date: 2009.
10. **Planned**: IPM014. Sample size: 40. Estimated completion date: late 2008.

EC

1. **Completed:** Phase 3 study of the efficacy and safety of the microbicide Carraguard® in preventing HIV seroconversion in women.
2. **Completed:** Qualitative evaluation of the informed consent process in the Phase 3 study of the efficacy and safety of the microbicide Carraguard® in preventing HIV seroconversion in women.
3. **Completed:** An evaluation of the strategies for care and support of women who test positive for HIV during the "Phase 3 study of the efficacy and safety of the microbicide Carraguard® in preventing HIV seroconversion in women."
4. **Ongoing:** Assessing the reporting of sensitive behaviors in microbicide trials.
5. **Ongoing:** Microbicides acceptability: A qualitative study to explore social and cultural norms, interpersonal relations and product attributes.
6. **Planed:** Phase 3 multi-centre double blind randomized placebo controlled effectiveness and safely study to assess the role of Truvada in preventing HIV acquisition in women

FEE

1. **Completed**: HIV incidence and syphilis rates among MSM at high risk for HIV-1 infection (as part of study implemented by Impacta-Perú in five Andean cities).
2. **Ongoing**: Chemoprophylaxis for HIV in Men. Sample size: 400 MSM at high risk for HIV will be enrolled in Guayaquil-Ecuador.

ICRH

1. **Completed:** Adding the female condom to a peer education program with female sex workers in Mombasa.
2. **Completed:** Development and evaluation of affordable laboratory tools in treatment management of HIV-1 infected individuals in Kenya. BioViro Study.
3. **Completed:** Female controlled methods to reduce the incidence of sexually transmitted infections and HIV in women. The diaphragm acceptability study.
4. **Completed:** Mombasa Cervical Cancer Community Outreach Evaluation (EC-INCO).
5. **Completed:** Bacterial vaginosis study.

6. **Completed:** Improving the supply of blood for transfusion: Community attitudes towards blood donation in Coast Province, Kenya.
7. **Completed:** IMPACT female sex worker cross-sectional survey.
8. **Completed:** Operations research around the introduction of antiretrovirals in the management of HIV-1 infected individuals in Mombasa, Kenya.
9. **Completed:** Female sex workers incidence survey.
10. **Completed:** Cross-sectional survey of sexual and reproductive health among postpartum women in Mombasa.
11. **Completed:** Putting food on the table: An exploration of livelihood strategies and their role in maintaining nutritional status among ART patients.
12. **Completed:** Prevention with positives.
13. **Completed:** Mombasa cohort study for estimation of HIV-1 incidence.
14. **Completed:** Management of cervical squamous cell intraepithelial lesions in HIV infected women in Mombasa, Kenya: Effectiveness of cryotherapy and predictors of progression.
15. **Completed:** Reducing HIV/STI risks and improving treatment for male sex workers in Mombasa, Kenya.
16. **Completed:** Behavioral monitoring surveys for HIV/STI/TB/RH/FP/Malaria in Coast, Rift valley and major transport corridors of Kenya.
17. **Ongoing:** IPM 011. Sample size: 50. Estimated completion date: mid 2008.
18. **Ongoing:** PharmAccess African studies to evaluate resistance on monitoring of HIV drug resistance (PASER) on patients on highly active antiretroviral therapy. Sample size: 240. Estimated completion date: December 2010.
19. **Ongoing:** Impact of triple ART during pregnancy and breastfeeding on mother-to-child transmission of HIV and mother's health: The Kesho Bora Sample size: 310. Estimated completion date: November 2009.

INMENSA

1. **Ongoing**: A5175: A Phase 4, prospective, randomized open-label evaluation of the efficacy of once-daily protease inhibitor and once-daily non-nucleoside reverse transcriptase inhibitor-containing therapy combinations for initial treatment of HIV-1 infected individuals from resource-limited settings (PEARLS Trial). Sample size: 60. Estimated completion date: Oct 2008.
2. **Ongoing**: A5185s: Effect of initial antiretroviral treatment on genital compartment virus in individuals from diverse areas of the world. Sample size: 23. Estimated completion date: Oct 2008.
3. **Ongoing**: A5199: International neurological study. Sample size: 35. Estimated completion date: Oct 2008.
4. **Ongoing**: iPrEx: Chemoprophylaxis for HIV prevention in men. Sample size: 500. Estimated completion date: Jun 2010.
5. **Ongoing**: A5190: Assessment of safety and toxicity among infants born to HIV-1-infected women enrolled in antiretroviral treatment protocols in diverse areas of the world. Estimated completion date: Oct 2008.
6. **Planned**: AIN503/ A5217: A randomized study of treatment with emtricitabine/tenofovir df and lopinavir/ritonavir versus no therapy in newly infected HIV-1 infected subjects to determine whether potent antiretroviral therapy alters the virologic setpoint. Sample size: 15.
7. **Planned**: ACTG 5221: A strategy study of immediate versus deferred initiation of antiretroviral therapy for HIV-infected persons treated for tuberculosis with CD4 <200 cells/mm. Sample size: 50.
8. **Planned**: ACTG 5225: A Phase 1/2 dose finding study of high dose fluconazole treatment in AIDS-associated cryptococcal meningitis. Sample size: 30.
9. **Planned**: ACTG 5234: International trial of modified directly observed therapy versus standard of care for patients with first virologic failure on a non-nucleoside reverse transcriptase inhibitor-containing antiretroviral regimen. Sample size: 15.

ISIP

1. **Completed**: Population Council Phase 3 study of the efficacy and safety of the microbicide Carraguard in preventing HIV in women.
2. **Completed**: A sub study to determine the efficacy of the vaginal microbicide, Carraguard as an inhibitor of Human Papilloma Virus (HPV) infections.
3. **Completed**: An evaluation of the strategies for care and support of women who test positive for HIV during screening for the "Phase 3 study of the efficacy and safety of the microbicide Carraguard in preventing HIV in women."

4. **Closed**: HVTN 503: A multicenter double-blind randomized placebo-controlled Phase 2B test-of-concept study to evaluate the safety and efficacy of a 3-dose regimen of the clade B-based Merck Adenovirus serotype 5 HIV-1 gag/pol/nef vaccine in HIV-1-uninfected adults in South Africa. Sample Size: 300.
5. **Ongoing**: Characterization of the evolution of adaptive immune responses in acute HIV clade C virus infections–Acute infection study. Ongoing collaboration with UKZN. Sample size: ~10 at present. Estimated completion date: to time participants' CD4+ drops below 200.
6. **Ongoing**: Assessing the reporting of sensitive behaviors in microbicide trials (ACASI) Sample Size: 270. Estimated completion date: February 2008.

IST

1. **Completed**: COL-1492 microbicide trial.
2. **Completed**: Community randomized trial of gonorrhea presumptive treatment among FSWs.
3. **Completed**: Cellulose sulfate microbicide trial.
4. **Completed**: Impact assessment of the Benin FSW intervention on the HIV epidemiology in the general population. Sample size: 800 FSWs, 800 FSW clients, and 2500 numbers of the general population recruited. Estimated completion date: 2009.
5. **Completed**: Capacity building project to reinforce the local capacity in conducting preventive trials. Estimated completion date: 2009.

KCMC

1. **Completed:** IPM003
2. **Planned**: IPM011. Sample size: 50. Estimated completion date: late 2008.
3. **Planned**: IPM014. Sample size: 40. Estimated completion date: late 2008.
4. **Planned**: IPM 015. Sample size: 70. Estimated completion date: 2009.

KEMRI

1. **Ongoing**: Phase 1 microbicide trial. Sample size: 45. Estimated completion date: Dec 07.
2. **Ongoing**: Phase 1 male microbicide trial. Sample size: 30.
3. **Ongoing**: Phase 3 HSV-2 suppression trial in discordant couples: Sample size: 540 couples. Estimated completion date: May 08.
4. **Planned**: Phase 1 microbicide trial: Sample size: 50. Estimated start date: not yet determined. Estimated completion date: not yet determined.
5. **Planned**: Phase 3 PrEP trial in discordant couples: Sample size: 500 couples. Estimated start date: Jan 08.

LSHM

1. **Completed:** Phase 1/2 trial of 452 low risk women.
2. **Completed:** Studies on interactions between herpesvirus and STDs
3. **Completed:** Studies on biological and immunological aspects of HIV/STDs
4. **Completed:** HSV2 suppression trial in HIV/HSV coinfected women
5. **Planned**: Phase 2/3 trial of Invisible Condom. Sample size: 5,000 women.

MCR

1. **Completed**: Knowledge of HIV/AIDS in the Majakaneng community (Done in 4 other communities in previous years).
2. **Ongoing**: IPM100. Sample size: 800 (cross-sectional); 300 (cohort). Estimated completion date: July 2008.
3. **Planned**: IPM014. Sample size: 40. Estimated completion date: late 2008.
4. **Planned**: IPM019. Sample size: 40. Estimated completion date: 2009.

MDP MAW

LSHTM has been involved in an intensive program of research into HIV prevention in Mwanza, Tanzania since the late 1980s, in close collaboration with NIMR and AMREF.

1. 1990-1995: EU, community-randomized trial which showed that improved treatment services for STDs reduced HIV incidence by 40%
2. 1995-1996: EU Pilot Model studies
3. 1997-2002: EU and Irish Aid, community-randomized trial to measure the impact of an adolescent sexual health intervention (MEMA kwa Vijana trial)
4. 1999-2004: MRC, Sexual behavior of adolescents in rural Tanzania and the impact of an innovative sexual health intervention detailed studies of adolescent sexual behavior
5. 1997-2000: Wellcome Trust, study of the adverse effects of maternal syphilis on the outcome of pregnancy
6. 2001-2009: DFID/MRC, Microbicides Development Programme (MDP), large randomized controlled clinical trial
7. 2003-2007: Wellcome Trust, clinical trial on the clinical epidemiology of HSV-2 and the impact of HSV-2 suppressive therapy to reduce HIV acquisition and HIV & HSV-2 shedding
8. 2005-2007: MRC, detailed studies of HIV and HSV shedding and their interaction
9. 2005-2010: GFATM program working with the Kisesa cohort study to monitor the uptake and impact of ART
10. 2000-ongoing: Geita Gold Mine/Barrick: Mine Health Project: Prevalence surveillance for HIV/STI/Malaria control program in goldmines and surrounding communities
11. 2002-2006: WHO, Studies evaluating new diagnostic tests for sexually transmitted infections
12. 2006-2009: DFID and Irish Aid, MEMA kwa Vijana trial further survey
13. 2002-2005: Wellcome Trust, Population-based research on the association between migration, mobility and HIV infection
14. 2005-ongoing: DFID: NIMR Mwanza and LSHTM are partners in the DFID-supported Research Programme Consortium on Sexual and Reproductive Health and HIV. This Research Programme Consortium is directed by Professor David Mabey (Clinical Research Unit, LSHTM). John Changalucha (Director of NIMR Mwanza Centre) leads the Mwanza component.
15. 2006: Validation of BED assay for identifying recent HIV infections in Kisesa cohort
16. 2006: Health Metrics Network, Finding the best questions to identify adult AIDS deaths using Verbal Autopsy tools
17. 2005: UNICEF, Analysis of data on welfare of orphans and foster children in Kisesa
18. 2005: WHO SURVART initiative, Antenatal clinic based HIV surveillance in the era of ART
19. 2005: Wellcome Trust, ALPHA network for data analysis in African community-based HIV studies to facilitate collaboration in data analysis in five African HIV cohort studies
20. 2004: Mellon Foundation, Barriers to the Uptake of ART qualitative study of perceptions about ART access in Kisesa ward
21. 2004: UNAIDS, Impact of mobility on HIV prevalence estimates in cross sectional surveys to advise on biases in HIV prevalence estimates from surveys and surveillance, using data from Kisesa cohort
22. 2004: DFID, Impact and Uptake of ART in Kisesa ward, Tanzania to prepare cohort study for work on effects of anti-retroviral therapy for HIV
23. 2001-2003: EC, Population mobility as a risk factor for HIV spread comparative study of two cohorts
24. 2000-2003: UNICEF & Measure Evaluation, Effects of HIV on child mortality. Comparative study of child mortality and maternal HIV infection in 3 HIV cohort study sites in Africa
25. 1996: Wellcome Trust, Modeling the relationship between fertility in HIV positive and HIV negative women in Africa analysis of data from Kisesa cohort study
26. 1990: ODA Research grant, Pilot of Preceding Birth Technique for measuring child mortality in Tanzania a baseline study for various NIMR/LSHTM HIV research intervention projects
27. 2007-2009: European and Developing Countries Clinical Trials Partnership (EDCTP); Clinical trials capacity building (GCP standards) and feasibility study to assess potential cohort suitability for future microbicide trials in northwest Tanzania
28. 2008-9: GlaskoSmithKline Biologicals' randomized controlled multicentre trial to assess the immunogenicity and safety of GSK's HPV-16/18 L1 AS04 vaccine in healthy female subjects aged 10-25 years.

MUMS

1. **Completed**: CS microbicide trial (2005-07)

MIRIAM

1. **Completed:** HIVNET 009
2. **Completed:** HPTN 020
3. **Completed:** HPTN 049
4. **Completed:** HPTN 050

MRC DUR

1. **Completed:** Population Council Phase 1 RCT
2. **Ongoing**: SPARTAC. Sample size: 80. Estimated completion date: 2010.
3. **Planned**: IPM011. Sample size: 50. Estimated completion date: late 2008.

MRC HLA

1. **Completed:** HPTN 055: Microbicide preparedness study.
2. **Ongoing**: HPTN 035: Phase 2/2B safety and effectiveness study of the vaginal microbicides BufferGel and 0.5% PRO 2000/5 gel (P) for the prevention of HIV infection in women.
3. **Planned**: MTN 015: An observational cohort study of women who became infected with HIV during their participation in MTN trials that aims to understand how the use of microbicides or oral prevention at the time of infection may affect the natural history and progression of HIV.

MUDHOL

1. **Completed:** Community prevalence study of HIV and STIs in Bagalkot district.
2. **Completed:** Assessment of barriers to care in prevention of mother-to-child HIV transmission programs in Karnataka—A qualitative study.
3. **Completed:** Assessment of care providers in Bagalkot district.
4. **Completed:** Determinants of diarrhoea among people living with HIV.
5. **Completed:** Behavioral assessment among female sex workers.
6. **Completed:** CONRAD Phase 3 randomized controlled trial of 6% Cellulose sulfate and the effect on vaginal transmission of HIV.
7. **Completed:** Behavioral and social science support of CONRAD Phase 3 clinical trial of cellulose sulfate 6% microbicide gel Bangalore/Bagalkot site.

PHIVA

1. **Ongoing**: IPM100. Sample size: 800 (cross-sectional); 300 (cohort). Estimated completion date: 2009.
2. **Planned**: IPM014. Sample size: 40. Estimated completion date: 2009.
3. **Planned**: IPM019. Sample size: 40. Estimated completion date: 2009.

PU

1. **Completed:** IPM003
2. **Ongoing:** HIV Incidence study - two populations in Rwanda: High-risk women and VCT clients. Sample size: 800 (cross-sectional, high-risk women), 300 (cohort, high risk women), 1250 (cross-sectional, VCT). Estimated completion date: June 2008.

QECH

1. **Ongoing**: HPTN 035
2. **Planned**: There are several microbicide trials in the preparation phase.

QM

1. **Ongoing**: IPM100. Sample size: 800 (cross-sectional); 300 (cohort). Estimated completion date: 2009.
2. **Planned**: IPM014. Sample size: 40. Estimated completion date: 2009.
3. **Planned**: IPM019. Sample size: 40. Estimated completion date: 2009.

RHRU-E

1. **Ongoing**: IPM100. Sample size: 800 (cross-sectional); 300 (cohort). Estimated completion date: 2009.
2. **Planned**: IPM014. Sample size: 40. Estimated completion date: 2009.

RHRU-O

1. **Completed**: Cohort retention study. Sample size: 750 women. Follow-up for one year.
2. **Ongoing**: MDP 301. Sample size: 2500 women. Estimated completion date: June 2008 (enrollment), June 2009 (follow-up).

RHRU-S

1. **Completed**: Cohort retention study. Sample size: 750 women. Follow-up for one year.
2. **Ongoing**: MDP 301. Sample size: 2500 women. Estimated completion date: June 2008 (enrollment), June 2009 (follow-up).

RHRU-Y

1. **Completed**: Acidform gel and diaphragm trial (2005).
2. **Completed**: IPM003 (2006).
3. **Ongoing**: IPM011. Sample size: 50. Estimated completion date: February 2008.
4. **Planned**: IPM014. Sample size: 40. Estimated completion date: late 2008.
5. **Planned**: IPM015/019. Sample size: 70. Estimated completion date: 2009.

RK KHAN

1. **Completed**: HPTN 055
2. **Ongoing**: HPTN 035
3. **Planned**: MTN 015

SRC

1. **Completed**: Phase 3 study of the efficacy and safety of the microbicide Carraguard® in preventing HIV seroconversion in women.
2. **Completed**: Qualitative evaluation of the informed consent process in the Phase 3 study of the efficacy and safety of the microbicide Carraguard® in preventing HIV seroconversion in women.
3. **Completed**: An evaluation of the strategies for care and support of women who test positive for HIV during the “Phase 3 study of the efficacy and safety of the microbicide Carraguard® in preventing HIV seroconversion in women.”
4. **Completed**: A sub-study to determine the efficacy of the vaginal microbicide Carraguard® as an inhibitor of human papilloma virus infection.
5. **Completed**: Evaluation of the strategies for care and support for women testing positive at pre-enrollment screening visit Population Council Protocol 369.
6. **Completed**: Assessing the reporting of sensitive behaviors in microbicide trials.
7. **Ongoing**: Microbicides acceptability: A qualitative study to explore social and cultural norms, interpersonal relations and product attributes.

8. **Ongoing**: Truvada Social, Behavioral and Community Preparedness Research
9. **Planned**: Insertion and counseling study in the use of LNG-IUS (Mirena).
10. **Planned**: Male tolerance study of PC815 compared to Carraguard following multiple applications.
11. **Stopped**: A Phase 2B test-of-concept, randomized, double-blind, placebo-controlled, international clinical trial to evaluate the efficacy, safety and immunogenicity of a multiclade HIV-1 DNA plasmid vaccine, VRC-HIVDNA016-00-VP, followed by a multiclade recombinant adenoviral vector vaccine, VRC-HIVADV014-00-VP, in HIV-uninfected persons.
12. **Planned**: A randomized, multicenter, double-blind study to compare the efficacy of single-day treatment (1000 mg b.i.d.) with famciclovir compared to that of placebo in patient-initiated episodic treatment of recurrent genital herpes in immunocompetent black patients.
13. **Planned**: Phase 3, multi center, double blind, randomized, placebo-controlled, effectiveness and safety study to assess the role of Truvada in preventing HIV acquisition in women.

THAI

1. Observational epidemiology studies including preparatory cohort, AIDSVAX B/E HIV Vaccine Trial, Vaccine Trial Extension Study, Bangkok Tenofovir Study.

UAB

1. **Completed**: HPTN 049 (Multiple clinical trials in all phases have been conducted by the other clinical trial networks. A list can be supplied as needed).
2. **Ongoing**: HPTN 059 (enrollment completed).
3. **Planned**: MTN 005

UN

1. **Completed**: Monthly antibiotic chemoprophylaxis and incidence of sexually transmitted infections and HIV-1 infection in Kenyan sex-workers—A randomized trial (azithromycin study).
2. **Completed**: Sustained reduction in sexual risk taking by female sex workers after participation in a randomized HIV prevention trial.
3. **Completed**: Prevalent herpes simplex virus type 2 infection is associated with altered vaginal flora and an increased susceptibility to multiple sexually transmitted infections.
4. **Completed**: Asymptomatic N. gonorrhoea co-infection at the time of HIV acquisition is associated with enhancement of HIV-specific DCS+T cell responses.
5. **Completed:** HIV neutralizing IgA in the genital tract of high-risk Kenyan sex-workers is prospectively associated with protection against sexual acquisition of HIV.
6. **Completed:** Does diaphragm use fit with the intravaginal practices of female sex workers in Nairobi, Kenya?
7. **Planned**: SBC preparation for Truvada clinical trial

UNC

1. **Completed**: HPTN 016
2. **Completed**: HPTN 016A
3. **Completed**: HPTN 024
4. **Completed**: SAFEST 1
5. **Completed**: GUD study
6. **Completed**: Trichomonas study
7. **Ongoing/Planned**: HPTN 035. Sample size: 600 women. Estimated completion date: 2008.
8. **Ongoing/Planned**: HPTN 052. Sample size: 250 couples. Estimated completion date: 2012.
9. **Ongoing/Planned**: BAN STUDY. Sample size: 2500 mother-infant pairs. Estimated completion date: 2009.

10. **Ongoing/Planned**: ACTG 5175. Sample size: 110 participants. Estimated completion date: 2008.
11. **Ongoing/Planned**: ACTG 5185. Sample size: 80 participants. Estimated completion date: 2008.
12. **Ongoing/Planned**: ACTG 5199. Sample size: 80 participants. Estimated completion date: 2008.
13. **Ongoing/Planned**: ACTG 5208. Sample size: 64 women. Estimated completion date: 2008.
14. **Ongoing/Planned**: CHAVI 001. Sample size: 220 participants. Estimated completion date: 2014.
15. **Ongoing/Planned**: CHAVI 011. Sample size: 300 participants. Estimated completion date: 2008.
16. **Ongoing/Planned**: IMPAACT 1041. Sample size: 60 children. Estimated completion date: 2009.
17. **Ongoing/Planned**: SAFEST 2. Sample size: 82 participants. Estimated completion date: 2008.
18. **Ongoing/Planned**: MTN 003.
19. **Ongoing/Planned**: MTN 015.
20. **Ongoing/Planned**: MALARIA PRE-055. Sample size: 200 children. Estimated completion date: 2008.
21. **Ongoing/Planned**: MALARIA 055. Sample size: 1200 children. Estimated completion date: 2011.
22. **Ongoing/Planned**: TRUVADA FORMATIVE. Estimated completion date: 2008.
23. **Ongoing/Planned**: TRUVADA STUDY. Sample size: 300 women. Estimated completion date: 2010.

UPENN

1. **Ongoing**: HPTN 035

UPITT

1. **Planned**: MTN 001
2. **Planned**: MTN 002

USF

1. **Ongoing**: MTN 004

UTH

1. **Completed**: Feasibility study for MDP 301 trial
2. **Completed**: Pilot study for MDP 301 trial
3. **Ongoing**: MDP 301. Sample size: 1330. Estimated completion date: April 2009.

UVRI

1. **Completed**: A randomized placebo controlled trial to assess the safety of 4% intravaginal dextrin sulphate gel at a Kampala Hospital, Uganda.
2. **Completed**: A randomized placebo controlled trial to assess the safety of 0.5% and 2% PRO 2000 gel 4% intravaginal dextrin sulphate gel at a Kampala Hospital, Uganda.
3. **Completed**: A community randomized trial of sexual behaviour and syndromic STI management interventions on HIV-1 transmission in rural Uganda.
4. **Ongoing**: An international multi-center, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% and 2% PRO 2000/5 gels for the prevention of vaginally acquired HIV infection. Sample size: 9755. Estimated completion date: March 2009.
5. **Ongoing**: DART Trial: Evaluation of different ART monitoring strategies in adults. Sample size: 3300 adults. Estimated completion date: 2008.
6. **Ongoing**: ARROW Trial: Evaluation of different ART monitoring strategies in children. Sample size: 1200 children. Estimated completion date: 2012.
7. **Ongoing**: Cryptococcal trial: Evaluation of an intervention (fluconazole) to prevent cryptococcal disease among adults. Sample size: 1420 adults. Estimated completion date: 2008.
8. **Ongoing**: SPARTAC Trial: Evaluation of ART provided in early HIV infection.

9. **Planned**: Phase 2B HIV vaccine trial (multicenter) to evaluate the efficacy, safety, and immunogenicity of a multiclade HIV-1 DNA plasmid vaccine, VRC-HIVDNA016-00-vp, followed by a multiclade recombinant adenoviral vector vaccine, VRC-HIVADV014-00-VP, in HIV-uninfected persons. Estimated start date: early 2008.

UZ-UCSF

1. **Completed**: Hormonal contraception and the risk of HIV acquisition.
2. **Completed**: Condom promotion study (HPTN016).
3. **Completed**: HIV risk reduction through HSV-2 prevention (ancillary to HPTN 016A).
4. **Completed**: Acceptability of diaphragm use to prevent HIV and STIs (DAS).
5. **Completed**: The latex diaphragm to prevent HIV acquisition among women: a female-controlled physical barrier of the cervix (MIRA).
6. **Completed**: Protein Specific Antigen (substudy to MIRA).
7. **Completed**: Phase 1 clinical trial of BufferGel.
8. **Completed**: Use of vaginal desiccants in association with HIV and STDs.
9. **Completed**: The reliability of ACASI data collection in Zimbabwe.
10. **Completed**: Acceptability of barrier contraceptives to prevent HIV/STDs.
11. **Completed**: A randomized trial of HIV prevention in Harare beerhalls.
12. **Completed**: Regai Dzive Shiri: A randomized trial of HIV/STD prevention in Zimbabwean youth.
13. **Completed**: A pilot study of acceptability of cervical barriers in at-risk youth.
14. **Completed**: Phase 1 safety trial of the diaphragm and cellulose sulfate in Zimbabwe.
15. **Completed**: Clinical trial to evaluate the safety and acceptability of nonoxynol-9 gel.
16. **Completed**: Screening of cervical cancer by visual inspection with acetic acid.
17. **Ongoing**: HIV related oral disease and human herpes virus 8 infection among women in Harare.
18. **Ongoing**: Phase 3 trial to determine the efficacy and safety of an extended regimen of nevirapine in infants born to HIV infected women to prevent vertical HIV transmission during breastfeeding (HPTN046). Sample size:550 mother infant pairs. Estimated completion date: March 2009.
19. **Ongoing**: Safety and effectiveness of BufferGel and PRO 2000/5 vaginal microbicides for the prevention of HIV infection in women (HPTN035). Sample size: 800. Estimated completion date: October 2009.
20. **Ongoing**: Phase 3, randomized, double-blind, placebo-controlled trial of acyclovir for the reduction of HIV acquisition among high-risk HSV-seropositive, HIV-seronegative individuals (HPTN039). Sample size: 400. Estimated completion date: October 2007.
21. **Ongoing**: Phase 3 randomized placebo-controlled trial of HSV-2 suppression to prevent HIV transmission among HIV-discordant couples (HPTN052). Sample size: 250 couples. Estimated completion date: December 2013.
22. **Ongoing**: Effect of hormonal contraception on HIV genital shedding among women with primary HIV infection. Sample size: 130. Estimated completion date: September 2010.
23. **Ongoing**: Microbicide acceptability (ancillary study to HPTN 035). Estimated completion date: October 2007.
24. **Ongoing**: Adolescent livelihood project. Sample size: 200. Estimated completion date: June 2008.
25. **Ongoing**: A randomized trial of community based volunteer counseling and testing. Community sample. Estimated completion date: June 2008.
26. **Ongoing**: SBC: Social and behavioral community activities in preparation for a PREP trial. Estimated completion when Truvada PREP trial will be completed (see below).
27. **Ongoing**: A5175 - A prospective, randomized, open-label evaluation of the efficacy of once-daily protease inhibitor and once-daily non-nucleoside reverse transcriptase inhibitor-containing therapy combinations for initial treatment of HIV-1 infected individuals from resource-limited settings (OEARLS) trial. Sample size: 100. Estimated completion date: 2009.
28. **Ongoing**: A5208 - Optimal combination therapy after nevirapine exposure. Sample size: 120. Estimated completion date: 2009.
29. **Ongoing**: A5190/P1054 - Assessment of safety & toxicity among infants born to HIV-infected women enrolled in ARV treatment protocols in diverse areas of the world. Sample size: pending. Estimated completion 2008.

30. **Ongoing**: A5199 - Neuropsychological assessment of patients initiating antiretroviral therapy in resource-limited settings. Sample size: 100. Estimated completion date: 2009.
31. **Ongoing**: A5185 (substudy to A5175) - Effect of initial antiretroviral treatment on genital compartment virus in individuals from resource-limited settings. Sample size: 350. Estimated completion date: 2009.
32. **Ongoing**: P1060 - A Phase 2, parallel, randomized, clinical trial comparing responses to initiation of NNRTT-based versus PI -based antiretroviral therapy in HIV-infected infants who have not previously received single dose nevirapine for prevention of mother-to child HIV transmission.
33. **Ongoing**: Behavioural and social science study. Estimated completion date: 2007.
34. **Ongoing**: Diaphragm provider study. Estimated completion date: 2007.
35. **Planned:** Phase 3, multi-center, double-blind, randomized, parallel, placebo-controlled effectiveness and extended safety study to assess the role of TRUVADA as prophylaxis to prevent HIV acquisition in women.
36. **Planned:** Non-pneumatic anti-shock garment for obstetrical hemorrhage.
37. **Planned:** Feasibility of using Duet as a menstrual cup in Zimbabwe.
38. **Planned:** Acceptability of Duet™ in African women.
39. **Planned:** HIV and pregnancy study.

YRG (selected trials; list is not complete)

1. **Completed**: HPTN 033
2. **Completed**: ART structured intermittent therapy
3. **Completed**: IAVI Phase 1 vaccine trial
4. **Completed**: CONRAD Phase 3 microbicide efficacy trial (CS gel)
5. **Ongoing**: CPOL study (NIMH). Sample size: 4300. Estimated completion date: August 2008.
6. **Ongoing**: AACTG 5175 (NIAID). Sample size: 130. Estimated completion date: January 2009.
7. **Ongoing**: Behavioral assessment and intervention among HIV serodiscordant couples (Yale/Duke University, NIH). Estimated completion date: August 2007.
8. **Ongoing**: AACTG-5190, 5122, 5230 (NIAID). Sample size: 100 each. Estimated completion dates: August 2009.
9. **Ongoing**: HIV and domestic violence (Ford Foundation). Sample size: 200. Estimated completion date: October 2007.
10. **Ongoing**: SHIELD intervention among IDU (NIH). Sample size: 200 index and 800 social network partners. Estimated completion date: August 2009.
11. **Ongoing**: HPTN052 (NIAID). Sample size: 250 serodiscordant couples. Estimated completion date: January 2012.
12. **Ongoing**: Psychosocial support to HIV positive women (APLA). Sample size: 1000. Estimated completion date: January 2008.

Appendix C: Publications

BLHC

1. Mayer KH, Maslankowski LA, Gai F, et al. Safety and tolerability of tenofovir vaginal gel in abstinent and sexually active HIV-infected and uninfected women. *AIDS* 20(4): 543-51, 2006.
2. El-Sadr WM, Mayer KH, Maslankowski L, et al. Safety and acceptability of cellulose sulfate as a vaginal microbicide in HIV-infected women. *AIDS* 20(8): 1109-16, 2006.

CAPRISA

1. Abdool Karim SS and Abdool Karim Q (eds). HIV/AIDS in South Africa. Cambridge University Press, Cape Town South Africa, 2005.
2. Abdool Karim SS. Microbicides for the prevention of HIV infection. In: HIV Sequence Compendium 2005, Leitner T, Foley B, Hahn B, Marx P, McCutchan F, Mellors J, Wolinsky S, and Korber B, editors. 2005. Published by Theoretical Biology and Biophysics Group, Los Alamos National Laboratory, LA-UR number 06-0680. pp30-40. Available at http://hiv.lanl.gov/content/hiv-db/COMPENDIUM/2005/partI/karim.pdf
3. Abdool Karim SS, Abdool Karim Q, Gouws E, Baxter C. Global Epidemiology of HIV. *Infectious Disease Clinics of North America* 21(1): 1-18, 2007.
4. Macqueen K, Abdool Karim Q. Adolescents and HIV clinical trials: ethics, culture, and context. *Journal of the Association of Nurses in AIDS Care* 18(2): 78-82, 2007.
5. Singh JA, Abdool Karim SS, Abdool Karim Q, et al. Ethico-legal challenges to the autonomous participation of adolescents in AIDS and other sensitive research in South Africa: lessons for the developing world. *PLoS Medicine* 3(7): e180, 2006.
6. Gaym A, Mashego M, Kharsany ABM, et al. Prevalence of abnormal Papanicoulau smears among young women in rural South Africa—implications for cervical cancer screening policies in high HIV prevalence populations. *South African Medical Journal* 97(2): 120-3, 2007.

CIDRZ

1. MacQueen KM, Namey E, Chilongozi D, et al. Community perspectives on care options for HIV prevention trial participants. *AIDS Care* 19(4): 554-60, 2007.
2. Brahmi A, Reid C, Masse B, Kelly C. Meeting retention challenges in Lusaka, Zambia. *Research Practitioner* 7(6): 212-3, 2006.
3. Fawal H, Reid CA. Microbicide Trials in the US (HPTN 049) and Zambia (HPTN 055): Lessons learned in two sister sites. Poster Presentation XV International AIDS Conference, Bangkok Thailand, 2004.

ICRH

1. Geibel S, Luchters S, King'ola N, et al. Factors associated with unprotected anal sex among male sex workers in Mombasa, Kenya. *Sexually Transmitted Diseases* Submitted.
2. Sarna A, Luchters S, Geibel S, et al. Short- and long-term efficacy of modified directly-observed antiretroviral therapy in Mombasa, Kenya: a randomized trial. *AIDS* Submitted.
3. Steegen K, Luchters S, Dauwe K, et al. Effectiveness of antiretroviral therapy and development of drug resistance in HIV-1 infected patients in Mombasa, Kenya. *AIDS Research and Human Retroviruses* Submitted.
4. Luchters S, Chersich MF, Rinyiru A, et al. Impact of five years of peer-mediated interventions among female sex workers in Mombasa Kenya. *BMC Public Health* Submitted.
5. Luchters S, Sarna A, Geibel S, et al. Safer sexual behaviours after 12 months of antiretroviral treatment in Mombasa, Kenya: a prospective cohort. *AIDS Patient Care and Research* Submitted.
6. Steegen K, Luchters S, De Cabooter N, et al. Evaluation of two commercially available alternatives for HIV-1 viral load testing in resource-limited settings. *Journal of Virological Methods* 146(1-2): 178-87, 2007.
7. Chersich MF, Luchters SMF, Othigo J, et al. HIV testing and counselling for women attending child health clinics; an opportunity for entry to PMTCT and HIV treatment. *International Journal STD & AIDS* Accepted.

8. Chersich MF, Luchters SM, Yard E, et al. Morbidity in the first year postpartum among HIV-infected women in Kenya. 2007 Sep 25; Epub ahead of print.
9. Okal J, Stadler J, Ombidi W, et al. Secrecy, disclosure and accidental discovery: Perspectives of diaphragm users in Mombasa, Kenya. *Culture, Health & Sexuality* 10(1): 13-26, 2008.
10. Steegen K, Luchters S, Demecheleer E, et al. Feasibility of detecting HIV-1 drug resistance in DNA extracted from whole blood or dry blood spots. *Journal of Clinical Microbiology* 45(10): 3342-51, 2007.
11. Karani A, De Vuyst H, Luchters S, et al. The Pap smear for detection of bacterial vaginosis. *International Journal of Gynaecology & Obstetrics* 98(1): 20-3, 2007.
12. Chersich MF, Luchters SMF, and Temmerman M. Increasing the scope and intensity of interventions to prevent HIV infection in infants: Best interests of women and children. *Southern African Journal of HIV Medicine*, 2007.
13. Schroth A, Luchters S, Chersich MF, et al. Use of homemade diaphragm for dual protection against pregnancy and sexually-transmitted infections. *East African Medical Journal* 84(1): 35-7, 2007.
14. Luchters S, Chersich MF, Jao I, et al. Acceptability of the diaphragm in Mombasa Kenya, a six month prospective study. *European Journal of Contraception and Reproductive Health Care* 12(4): 345–53, 2007.
15. Chersich MF, Luchters SMF, Malonza IM, et al. Heavy episodic drinking among Kenyan female sex workers is associated with unsafe sex, sexual violence and sexually transmitted infections. *International Journal for STD & AIDS* 18(11): 764-9, 2007.
16. Geibel S, van der Elst EM, Kingola N, et al. “Are you on the market?” A capture-recapture enumeration of men who sell sex to men in and around Mombasa, Kenya. *AIDS* 21:1349-54, 2007.
17. Gallo MF, Behets FM, Steiner MJ, et al. Validity of self-reported “safe sex” among female sex workers in Mombasa, Kenya – PSA analysis. *International Journal of STD & AIDS* 18(1): 33-8, 2007.
18. Thomsen SC, Ombidi W, Toroitich-Ruto C, et al. A prospective study assessing the effects of introducing the female condom in a sex worker population in Mombasa. *Sexually Transmitted Infections* 82(5): 397–402, 2006.
19. Chersich MF, Urban MF, Venter FWD, et al. Efavirenz use during pregnancy and for women of child-bearing potential. *AIDS Research and Therapy* 3: 11, 2006.

INMENSA

1. Bautista CT, Sanchez JL, Montano SM, et al. Seroprevalence of and risk factors for HIV-1 infection among South American men who have sex with men. *Sexually Transmitted Infections* 80(6): 498-504, 2004.
2. Montano SM, Sanchez JL, Laguna-Torres A, et al. Prevalences, genotypes, and risk factors for HIV transmission in South America. *Journal of Acquired Immune Deficiency Syndromes* 40(1): 57-64, 2005.
3. Grant RM, Buchbinder S, Cates W Jr, et al. AIDS. Promote HIV chemoprophylaxis research, don't prevent it. *Science* 309(5744): 2170-1, 2005.
4. Zunt JR, La Rosa AM, Peinado J, et al. Risk factors for HTLV-II infection in Peruvian men who have sex with men. *American Journal of Tropical Medicine and Hygiene* 74(5): 922-5, 2006.
5. Lama JR, Sanchez J, Suarez L, et al. Linking HIV and antiretroviral drug resistance surveillance in Peru: A model for a third-generation HIV sentinel surveillance. *Journal of Acquired Immune Deficiency Syndromes* 42(4): 501-5, 2006.
6. Lama JR, Lucchetti A. Suarez L, et al. Association of herpes simplex virus type 2 infection and syphilis with human immunodeficiency virus infection among men who have sex with men in Peru. *Journal of Infectious Disease* 194(10): 1459-66, 2006.
7. Sanchez J, Lama JR, Kusunoki L, et al. HIV-1, sexually transmitted infections, and sexual behavior trends among men who have sex with men in Lima, Peru. *Journal of Acquired Immune Deficiency Syndromes* 44(5): 578-85, 2007.

ISIP

1. Mthembu PN, Kunene T, Govender T, et al. Retention challenges and strategies used to improve retention in the population council Phase III Carraguard Trial in Durban, South Africa. 3rd South African AIDS Conference, Durban ICC, 5-8 June 2007.
2. Ngubane MD, Mthembu PN, Palanee T, Ramjee G. Benefits of a detailed locator information combined with global positioning systems (GPS) in retention in the population council Phase III Carraguard Clinical trial in Durban, South Africa. 3rd South African AIDS Conference, Durban ICC, 5-8 June 2007.
3. Langa N, Makhanya N, Mngqundaniso N, et al. Couple counselling as a strategy to increase product adherence in the Phase 3 Carraguard trial in Durban, South Africa. 3rd South African AIDS Conference, Durban ICC, 5-8 June 2007.
4. Naidoo K, Govender T, Palanee T, Ramjee G. Women's dependence on the services provided by Population Council Phase III Carraguard microbicide trial. 3rd South African AIDS Conference, Durban ICC, 5-8 June 2007
5. Kunene TH, Palanee T, Ramjee G. Establishing comprehensive Memorandums of Understanding (MOUs) with service providers in the Phase 3, Carraguard Trial. 3rd South African AIDS Conference, Durban ICC, 5-8 June 2007.
6. Govender TJ, Samraj L, Naidoo K, et al. Introduction and uptake of female condoms by women enrolled in the Phase III Carraguard trial in Durban, South Africa. 3rd South African AIDS Conference, Durban ICC, 5-8 June 2007.
7. Makhanya N, Mbeje T, Palanee T, Ramjee G. Encouraging male involvement in HIV prevention trials for women. 3rd South African AIDS Conference, Durban ICC, 5-8 June 2007.
8. Gehret M, Skoler S, Littlefield S, et al. Correlation between male partner circumcision and HIV prevalence among screened participants in the Phase 3 Carraguard microbicide trial. 3rd South African AIDS Conference, Durban ICC, 5-8 June 2007.
9. Palanee T, Morar NS, Frank K, et al. HIV and STI prevalence among women screened at three sites within South Africa for inclusion in the Phase III Carraguard microbicide clinical trial. Microbicides 2006. 24-26 April 2006, Cape Town International Convention Centre, Cape Town, South Africa.
10. Mthembu N, Mthethwa S, Dlamini D, et al. Challenges in recruiting young women between the ages of 16 to 21 years in the Phase III Carraguard clinical trial in Durban, South Africa. Microbicides 2006. 24-26 April 2006, Cape Town International Convention Centre, Cape Town, South Africa.
11. Langa Z, Thebe T, Palanee T, et al. Syndromic management of STIs: Comparison between clinical and laboratory findings. Microbicides 2006. 24-26 April 2006, Cape Town International Convention Centre, Cape Town, South Africa.
12. Kunene TH, Palanee T, Thebe T, et al. Disclosure of HIV status among women screened for participation in the Carraguard Phase III trial in Durban, South Africa. Microbicides 2006. 24-26 April 2006, Cape Town International Convention Centre, Cape Town, South Africa.
13. Langa ZG, Thebe T, Cele N, et al**.** Problems encountered in treating woman with sexually transmitted infections in the Phase III Carraguard trial. Microbicides 2006. 24-26 April 2006, Cape Town International Convention Centre, Cape Town, South Africa.
14. Naidoo K, Palanee T, Ramjee G. Development of tools to improve syphilis treatment compliance among women in the Carraguard® Phase III trial . Microbicides 2006. 24-26 April 2006, Cape Town International Convention Centre, Cape Town, South Africa.
15. Giai-Minietti L, Naidoo K, Chetty NA, et al**.** Participant retention strategies in an ongoing Phase III Carraguard microbicide trial in Durban, South Africa. Microbicides 2006. 24-26 April 2006, Cape Town International Convention Centre, Cape Town, South Africa.
16. Pillay L, Palanee T, Vilakazi H, Ramjee G. Co-infections of Trichomonas vaginalis, Neisseria gonorrhoea and Chlamydia trachomatis in HIV positive women screened out in Carraguard, Phase III clinical trial site, Durban, South Africa. Microbicides 2006. 24-26 April 2006, Cape Town International Convention Centre, Cape Town, South Africa.
17. Palanee T, Govender T, Kizis F, et al. HIV and STI prevalence among women screened for inclusion in the Carragurad Phase III clinical trial in Durban, South Africa. SA AIDS Conference 2005, International Convention Centre, Durban, 7-10 June 2005.
18. Coumi N, Palanee T, Govender T, et al. Challenges in implementing the Carraguard microbicide Phase III clinical trial in Durban, South Africa. SA AIDS Conference 2005, International Convention Centre, Durban, 7-10 June 2005.

IST

1. Germain M, Alary M, Guèdèmè A, et al. Evaluation of screening algorithms for the diagnosis of genital infections with *Neisseria gonorrhoeae* and *Chlamydia trachomatis* among female sex workers in Benin. *Sexually Transmitted Diseases* 24: 109-115, 1997.
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11. Vickerman P, Watts C, Delany S, et al. The importance of context: model projections on how microbicide impact could be affected by the underlying epidemiological and behavioural situation in two African settings. *Sexually Transmitted Diseases* 33(6): 397-405, 2006.
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KEMRI

1. Lingappa JR, Lambdin B, Bukusi EA, et al; for the Partners in Prevention HSV-2/HIV Transmission Study Group. Regional differences in prevalence of HIV-1 discordance in Africa and enrollment of HIV-1 discordant couples into an HIV-1 prevention trial. *PLoS ONE* 9;3(1): e1411, 2008.
2. Ng'ayo MO, Bukusi E, Morrow RA, et al. Sexual and demographic determinants for Herpes Simplex Virus Type 2 among fishermen along Lake Victoria, Kenya. *Sex Transm Infect*, 2007 Dec 20; [Epub ahead of print].
3. Ng'ayo MO, Bukusi E, Rowhani-Rahbar A, et al. Epidemiology of human papillomavirus infection among fishermen along Lake Victoria Shore in the Kisumu District, Kenya. *Sex Transm Infect* (1): 62-6, 2008.
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LSHM

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MDP MAW

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YRG team has over 100 publications in different peer reviewed journals. Details are available at www.yrgcare.org.