

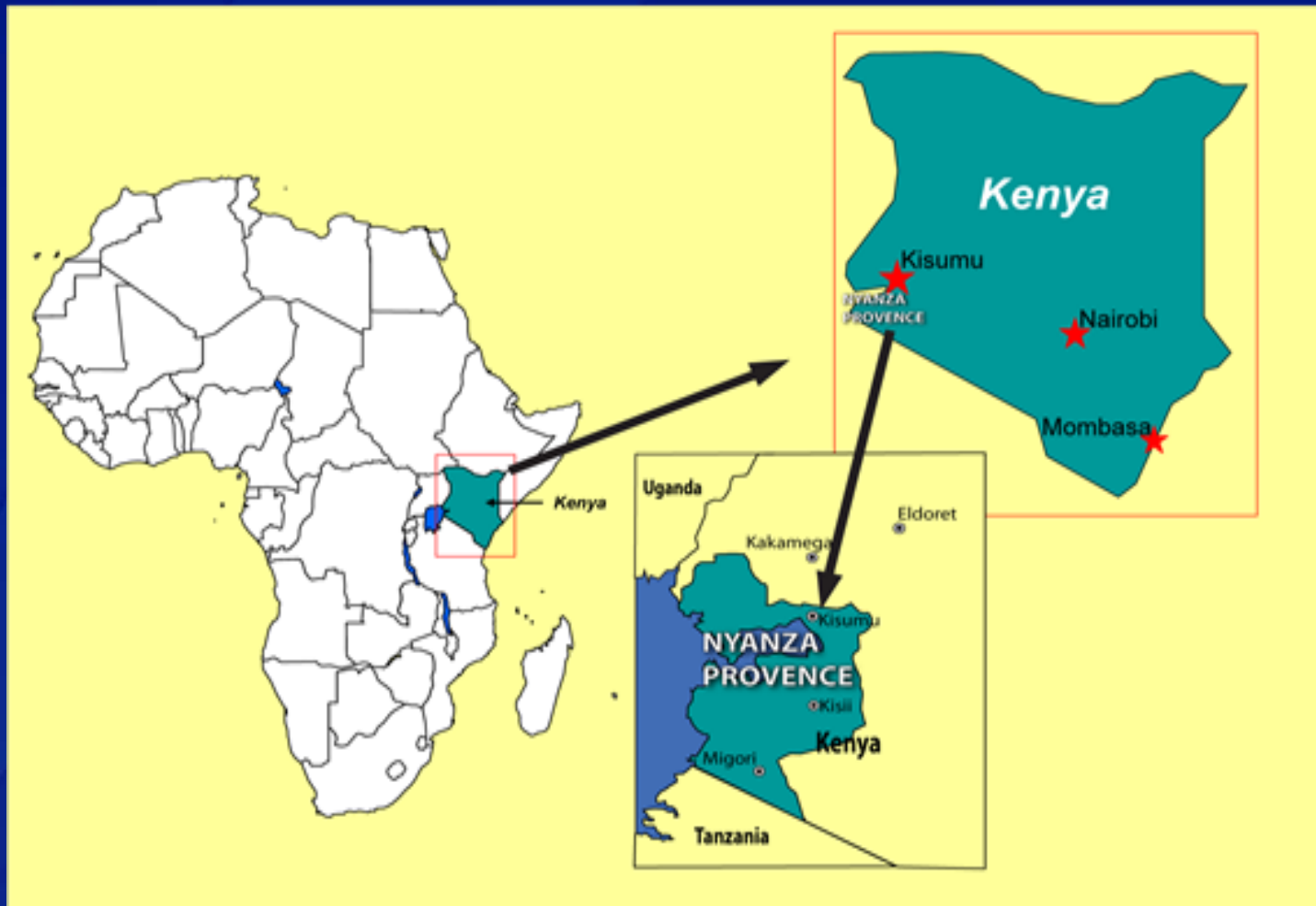
The Kisumu Clinical Research Site

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Overview

- History of the Kisumu CRS
- Communities Served by the Kisumu CRS
- Completed Studies / Clinical Trials
- Current Studies / Clinical Trials
- Nuvaring Experiences
- MTN 034 in Kisumu CRS

KISUMU CRS



History of the Kisumu CRS

- ❑ Main location is KEMRI Clinical Research Centre (CRC)
 - Campus of largest western Kenya referral hospital (JOO TRH)
- ❑ Kenya Medical Research Institute (KEMRI) / Centers for Disease Control and Prevention (CDC) partnership
- ❑ Became DAIDS Network CRS in December 2013
 - Emory CTU
 - ACTG network since 2013 and HPTN beginning in 2016

Communities Served

- ❑ Past studies included
 - ✓ General Population
 - ✓ Adolescents girls and boys
 - ✓ Discordant Couples
 - ✓ Female Sex workers
 - ✓ Men who have Sex with Men
 - ✓ Fisher Folk
 - ✓ Pregnant and breast feeding women
 - ✓ Women of reproductive potential

Research Capabilities

- KEMRI and CDC partner research programs
 - ✓ HIV
 - ✓ TB
 - ✓ Malaria
 - ✓ Emerging infections
 - ✓ NCDs
- Laboratory
 - ISO accredited HIV and TB laboratory
 - Regional WHO accredited HIV drug resistance reference Laboratory

Current / Completed studies

□ ACTG studies

- A5279, A5288, **A5316**, **A5297**, A5263, A5300, A5338, A5290, A5344, A5349 (TBTC Study 31), A5243

□ HPTN studies

- **HPTN 052**
- HPTN 075: observational cohort study to determine feasibility of recruiting MSM in preparation for HIV prevention studies in Africa
- HPTN 081 (AMP Study): VRC01 broadly neutralizing monoclonal antibody prevention of HIV-1

HPTN 052 rewarded for best recruitment award in 2010 and best retention awards for 2010 and 2011. HPTN 075 recognised for most innovative site in terms of community recruitment of MSM in 2016

Other HIV Specific Studies

- ❑ **Kisumu Breastfeeding Study (KiBS) – 2004-2009**
 - Demonstrated effective prevention of mother-to-child transmission and informed both WHO and Kenya national guidelines in 2009
- ❑ **KICOS Adolescent Study – 2010**
 - Successfully involved adolescents in HIV prevention research
- ❑ **Nuvaring Study – 2014-2015**
 - Examines adherence, acceptability and biological effects of intra-vaginal combined hormonal contraceptive ring among HIV (–) women
 - 53 participants were ≤ 21 years of age

Kisumu CRS Studies Involving Adolescents

| Study Number/Name | Age Range of Participants | Product | No. of participants enrolled |
|-------------------|---------------------------|------------------------|--|
| Moon Cup Study | 13-19 | Moon Cup menstrual cup | 3864 participants (966 per arm) in 84 clusters (21 schools per arm) |
| PIRE | 15-19 | Observational | 1500 |
| Game Study | 11-14 | Video Game | 108 participants to be enrolled; 48 participating in formative research and 60 in intervention) and their parents or caregivers. |

Nuvaring Experiences

Aim:

- To assess the adherence, acceptability and biologic effects of a hormonal contraceptive IVR among sexually active young women
- 692 pre-screened
- 302 participants enrolled
- 210 started on ring over 3 months
- Retention over the 6 months was 87%

Lessons Learned

- ❑ Comfort during invasive procedures like pelvic exams by using privacy and female clinicians
- ❑ Avoid too many invasive procedures
- ❑ Alleviate the fears of participants through counseling and demonstration of procedures
- ❑ Women whose partners knew about their involvement in the study generally had better adherence

Kisumu CRS and MTN 034

- ❑ High burden of HIV and unintended pregnancies among adolescents and young women in our region
- ❑ The site has conducted studies that have successfully involved adolescents (an underserved and critical population) in HIV prevention research

Planned Recruitment Strategies

- ❑ School based approaches
- ❑ Youth friendly centers and organizations
- ❑ Community Advisory Boards (CABs) & Youth Advisory Boards (YABs)
- ❑ Snowballing / peer-to-peer
- ❑ Community Healthcare Workers (CHEWs/ CHWs)
- ❑ Youth friendly activities and hotspots
 - e.g. youth based religious activities events and entertainments spots like discos and hang-out joints

Planned Retention Strategies

- ❑ Youth Friendly clinic that include flexible scheduling, re-scheduling, warm reception and short waiting time
- ❑ Adolescent entertainment such as TV and videos, indoor games and reading places and materials
- ❑ Transport assistance
- ❑ Reimbursement for study activities and appreciation packages
- ❑ Enhanced follow-up
 - Regular polite reminders for clinic appointments
 - Detailed locators and contact information followed by home verifications upon enrollment

Acknowledgements

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KEMRI CGHR

CDC ATLANTA