

**SINDAWONYE  
Clinical Trials Unit  
(we are together)**

**GITA RAMJEE**

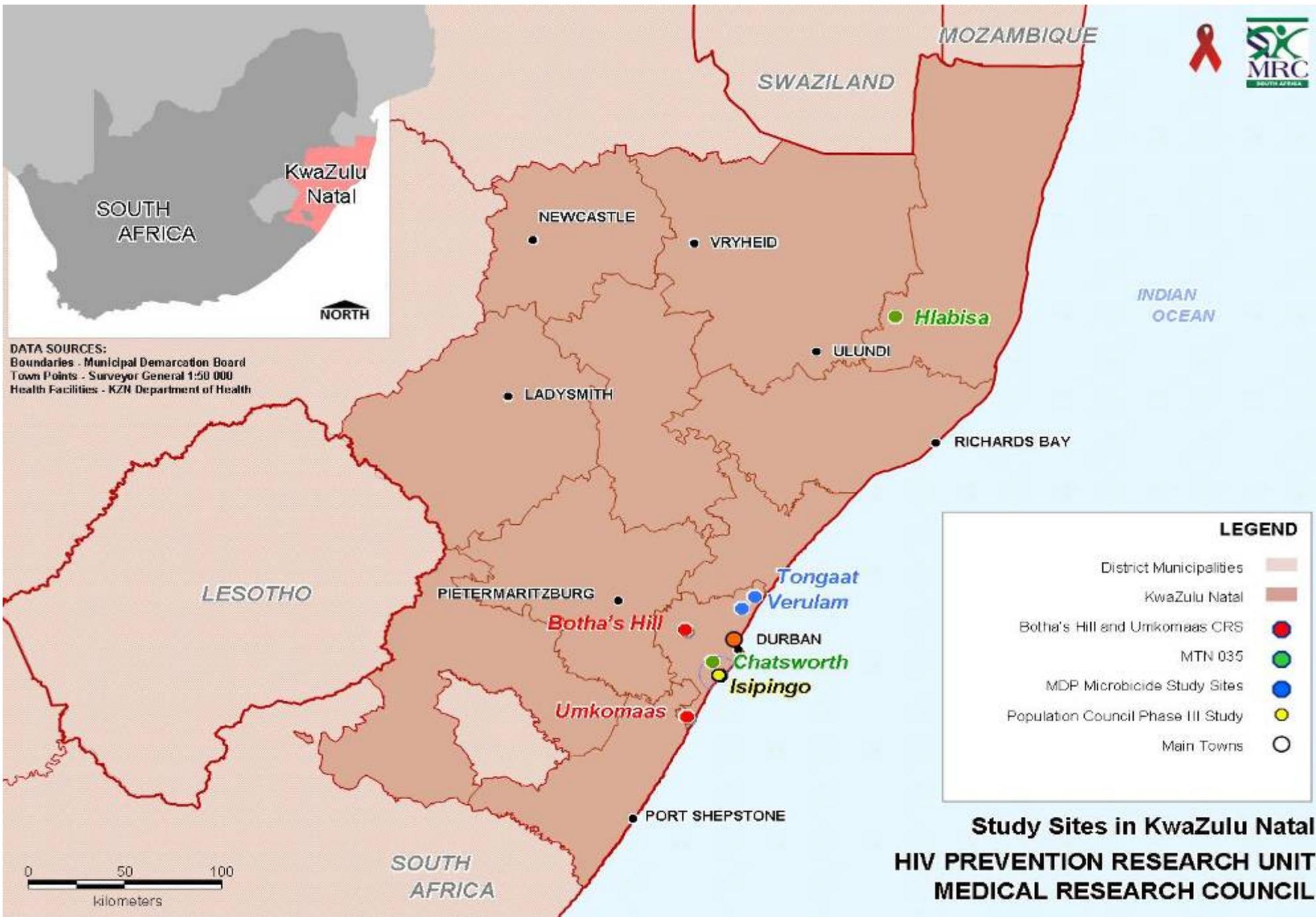
**MTN Regional Meeting, Cape Town, South Africa  
21-24 May 2007**



**South African Medical Research Council**

**BUILDING A HEALTHY NATION THROUGH RESEARCH**







SOUTH  
AFRICAN  
MEDICAL  
RESEARCH  
COUNCIL

# CHATSWORTH CRS



Building a healthy nation through research



## CHATSWORTH CRS

- 🚫 approximately 19 miles south of the main Westville CTU office**
- 🚫 Chatsworth is an urban area with about 20 informal (makeshift housing erected on vacant land) and 15 formal settlements**
- 🚫 It has a total population of 500 000 people from primarily the Indian (Asian) and African ethnic groups**



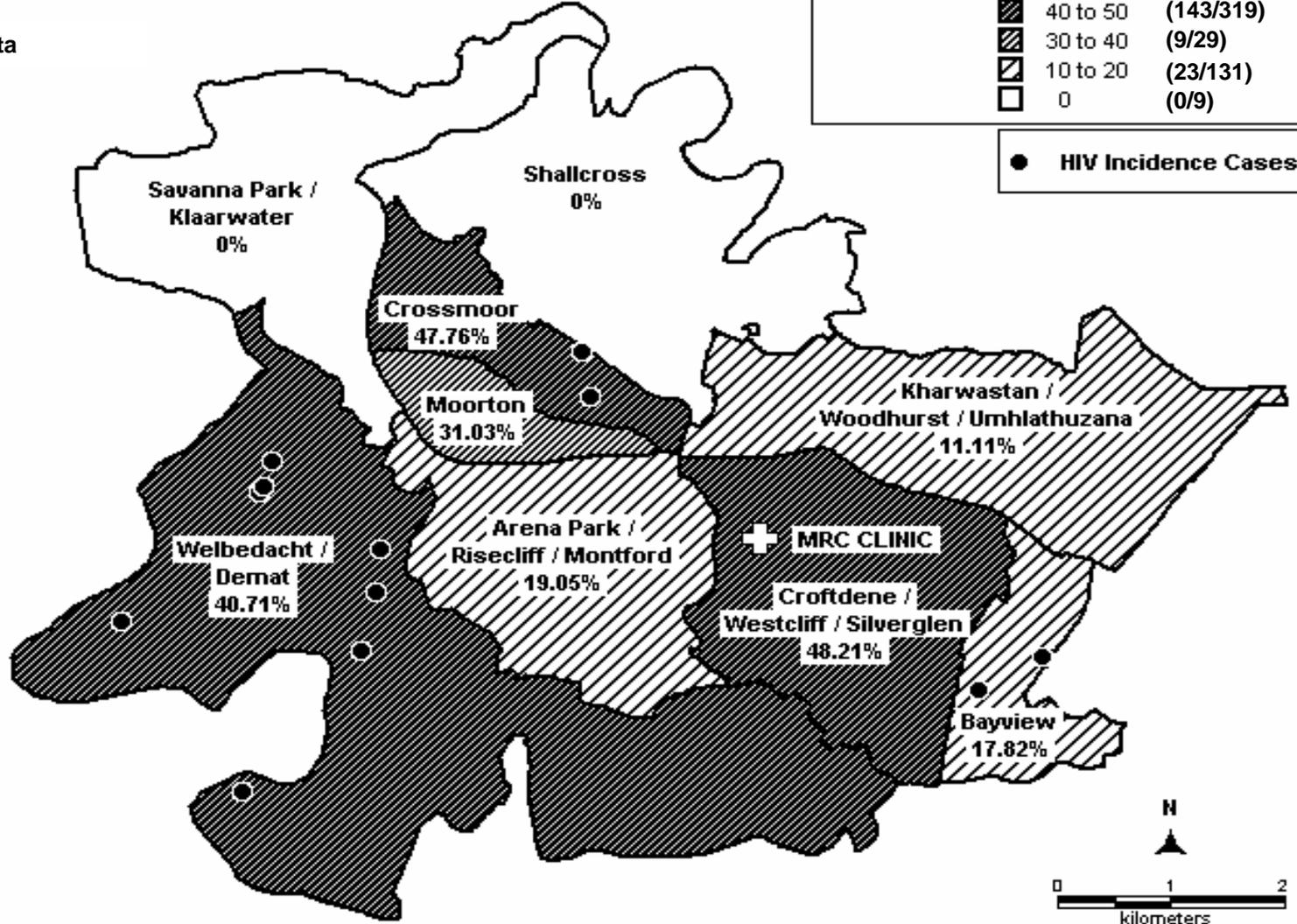
**HIV Prevalence Among Women Screened and HIV Incidence Cases Among Women Enrolled in the HPTN 055 HIV Prevention Preparedness Study By Neighbourhood Cluster**

055 Data

**Prevalence % Among Women Screened By Neighbourhood Cluster Assessed**

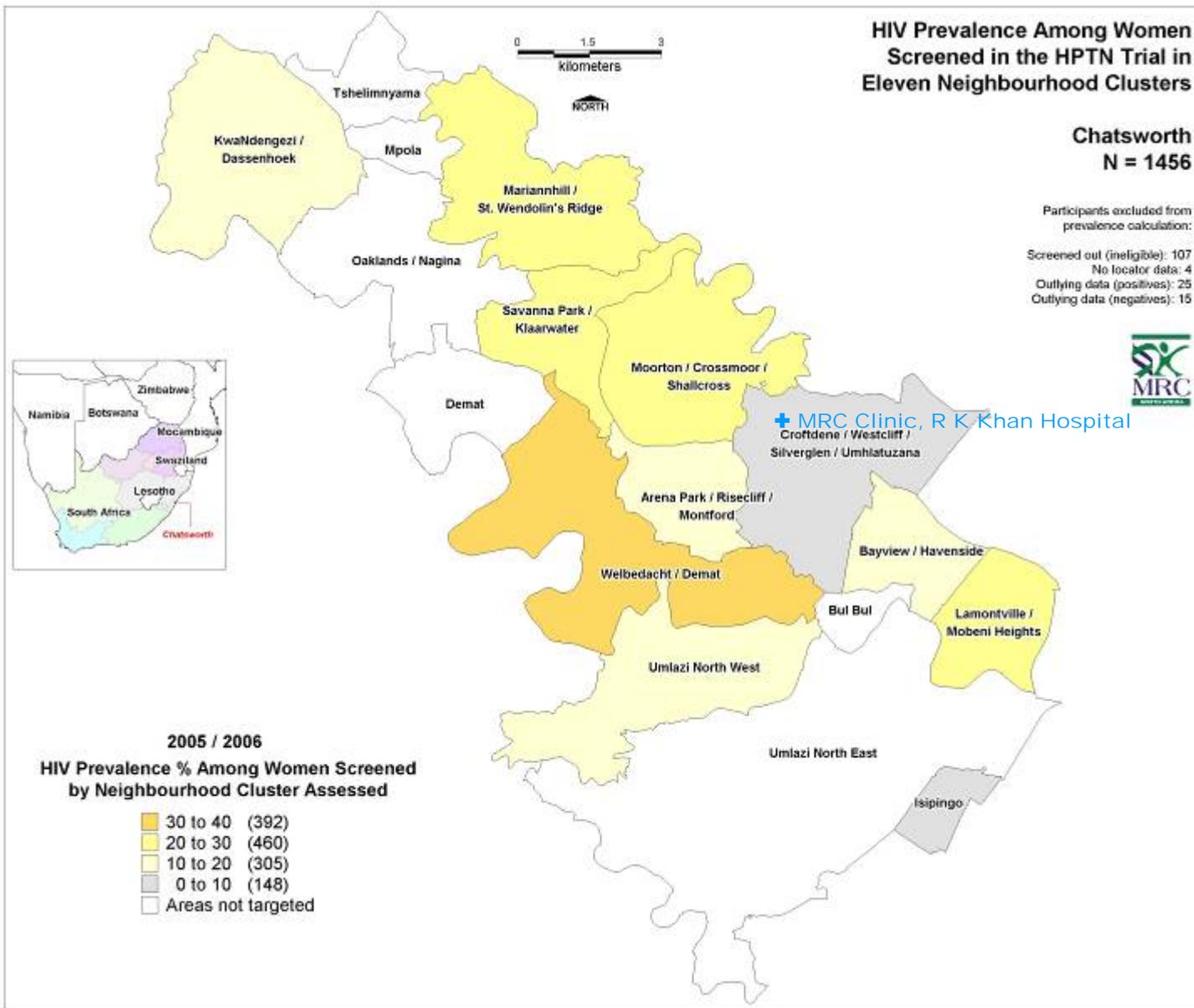
	40 to 50	(143/319)
	30 to 40	(9/29)
	10 to 20	(23/131)
	0	(0/9)

HIV Incidence Cases





Building a healthy nation through research



## Baseline Demographics of participants enrolled in the HPTN 055: Chatsworth CRS

<b>Ethnic Group</b>	
Zulu	43%
Indian	37%
Coloured	1%
White	<1%
Other African ethnic group	19%
<b>% Married</b>	30%
<b>Mean Age</b>	27.6 yrs
<b>Highest level of education</b>	
No schooling	5%
Primary (incomplete)	13%
Primary (complete)	6%
Secondary (incomplete)	55%
Secondary (complete)	20%
Tertiary	2%
<b>% Employed</b>	21%

## Baseline Sexual characteristics and sexual behaviour of participants enrolled in the HPTN 055 trial: Chatsworth CRS

<b>Mean # of male sexual partners, past 3 months</b>	1.1
<b>Vaginal sex without condom in past 3 months (%)</b>	83%
<b>Mean typical # sex acts in past 1 week</b>	2.0



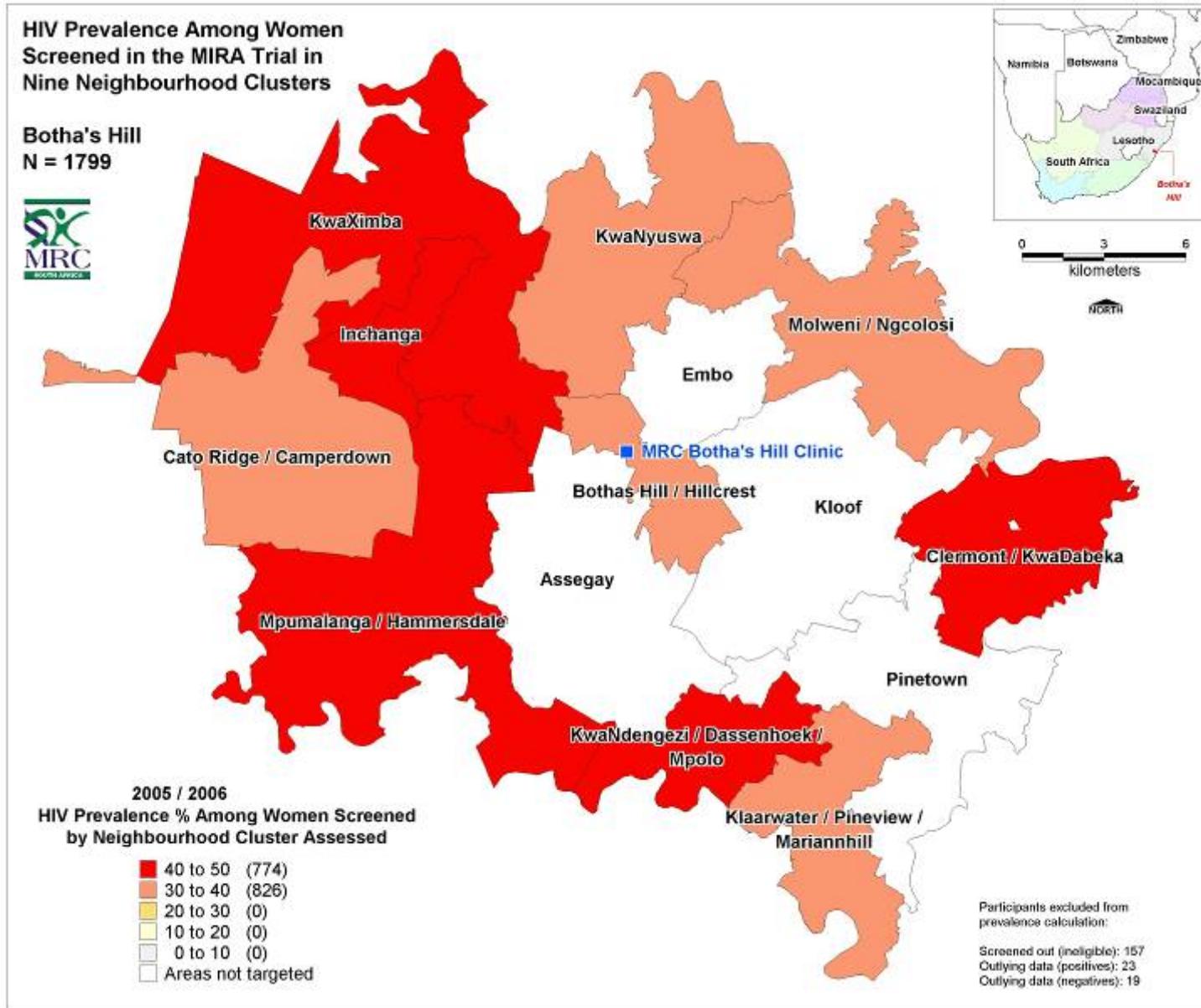
Building a healthy nation through research

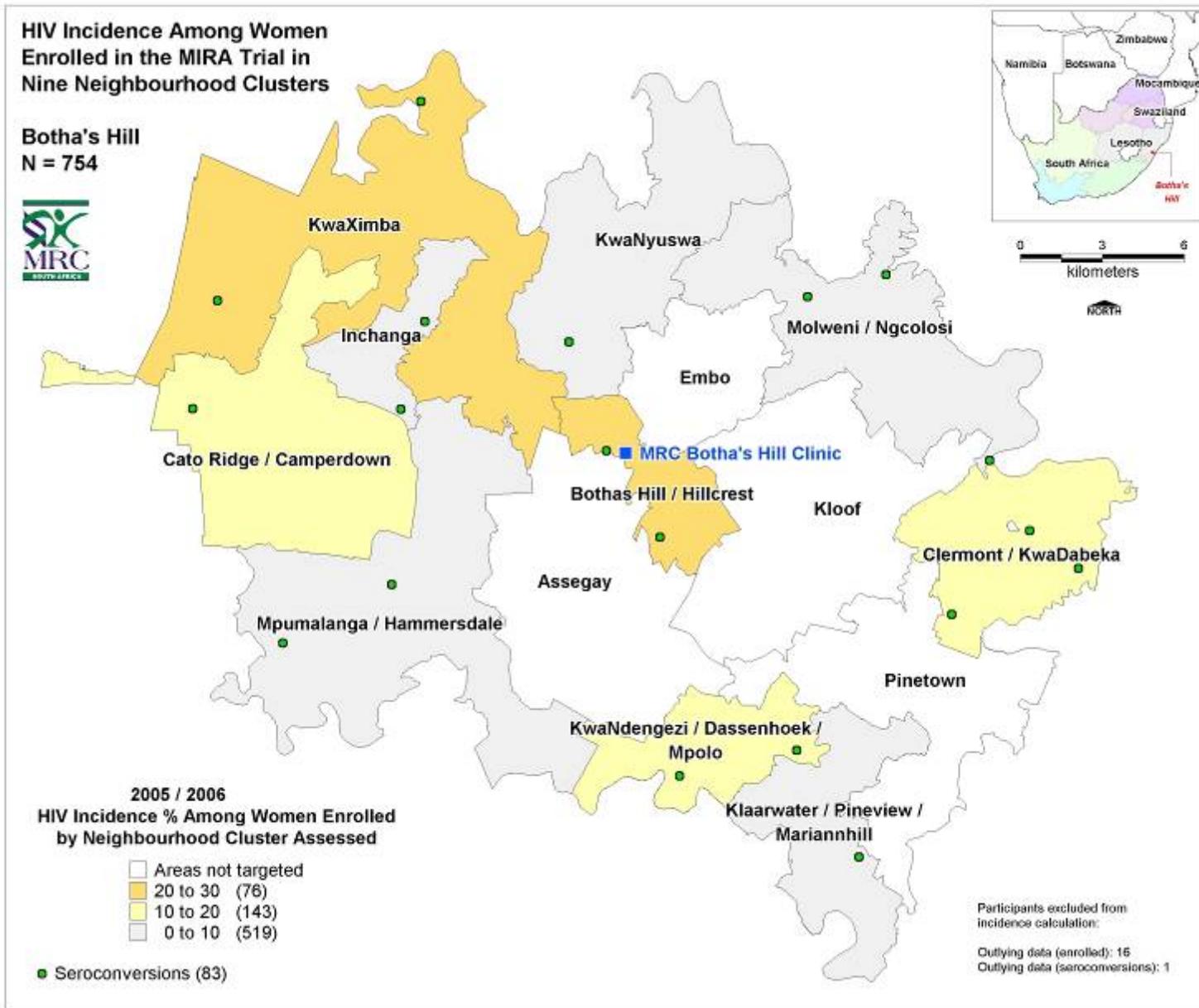


## **BOTHA'S HILL CRS**

**🚫 19 miles northwest of the central unit in Westville, Durban**

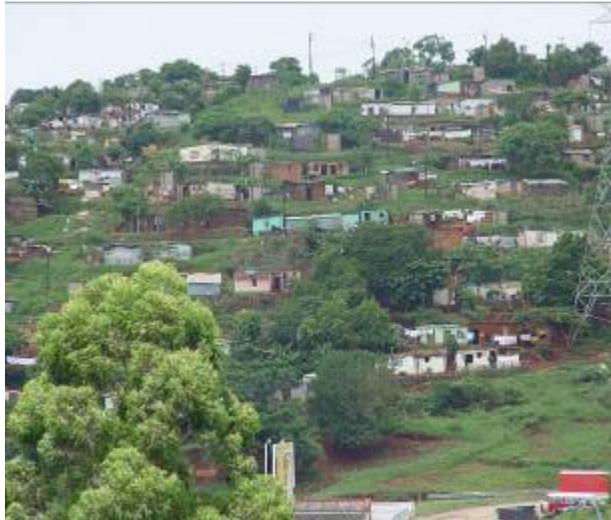
**🚫 Within the 9 mile radius of the research site, there is access to a total population of 462,531, of whom 218,799 (47.3%) are male and 243,732 (52.7%) are female.**







Building a healthy nation through research



## UMKOMAAS CRS

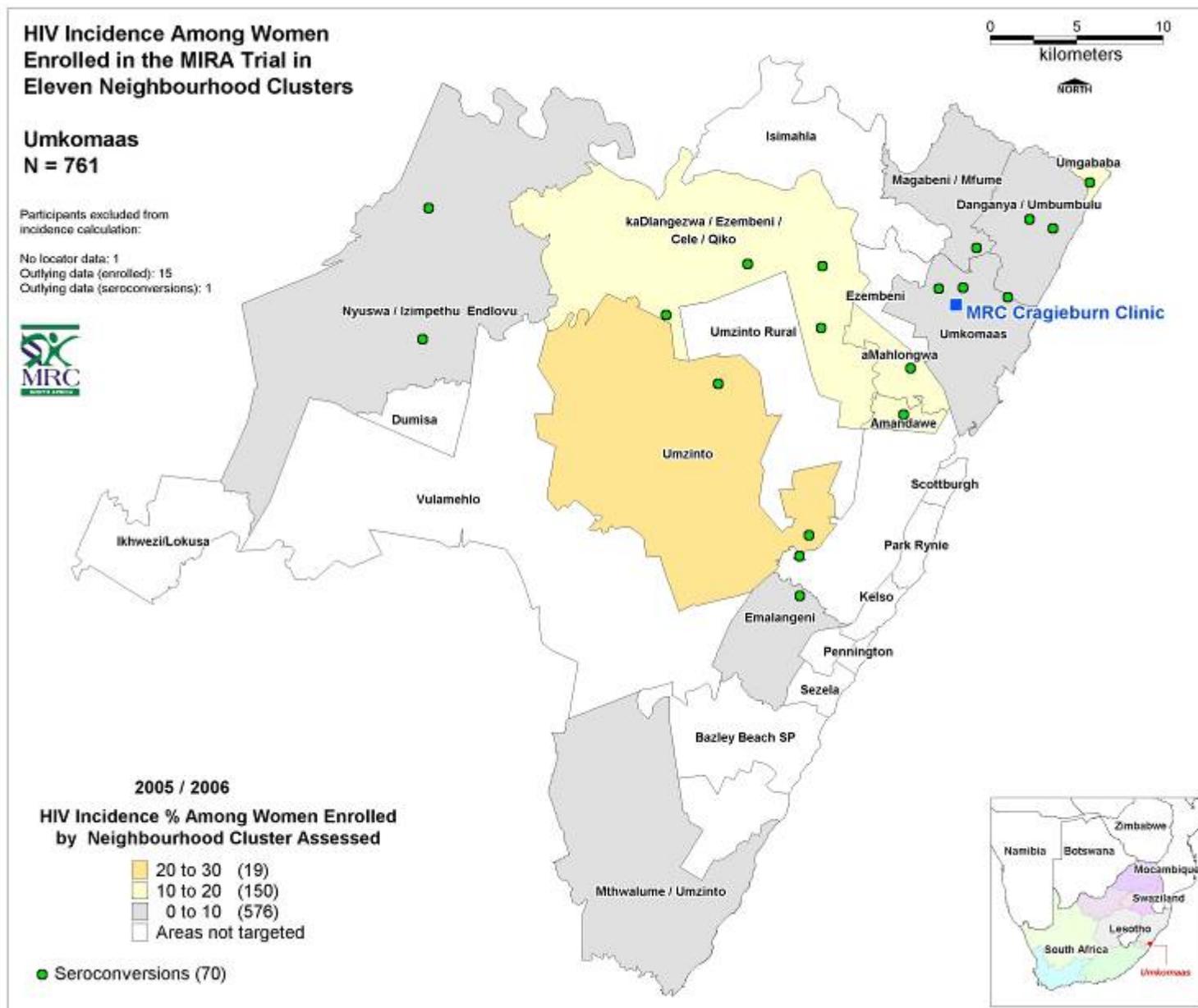
**🚫 Semi rural area**

**🚫 40 miles south of Durban**

**🚫 Formal and informal areas are populated mainly by African, Indian (Asian) and Colored ethnic groups**

**🚫 Population of 121,448 of whom 56,898 (46.9%) are male and 64,550 (53.1%) are female within a 9 mile radius of the clinic and 349,243 (46.8% male and 53.2% female) within a 15 mile radius**





## Baseline Demographics of participants enrolled in the MIRA trial: Umkomaas and Botha's Hill CRS

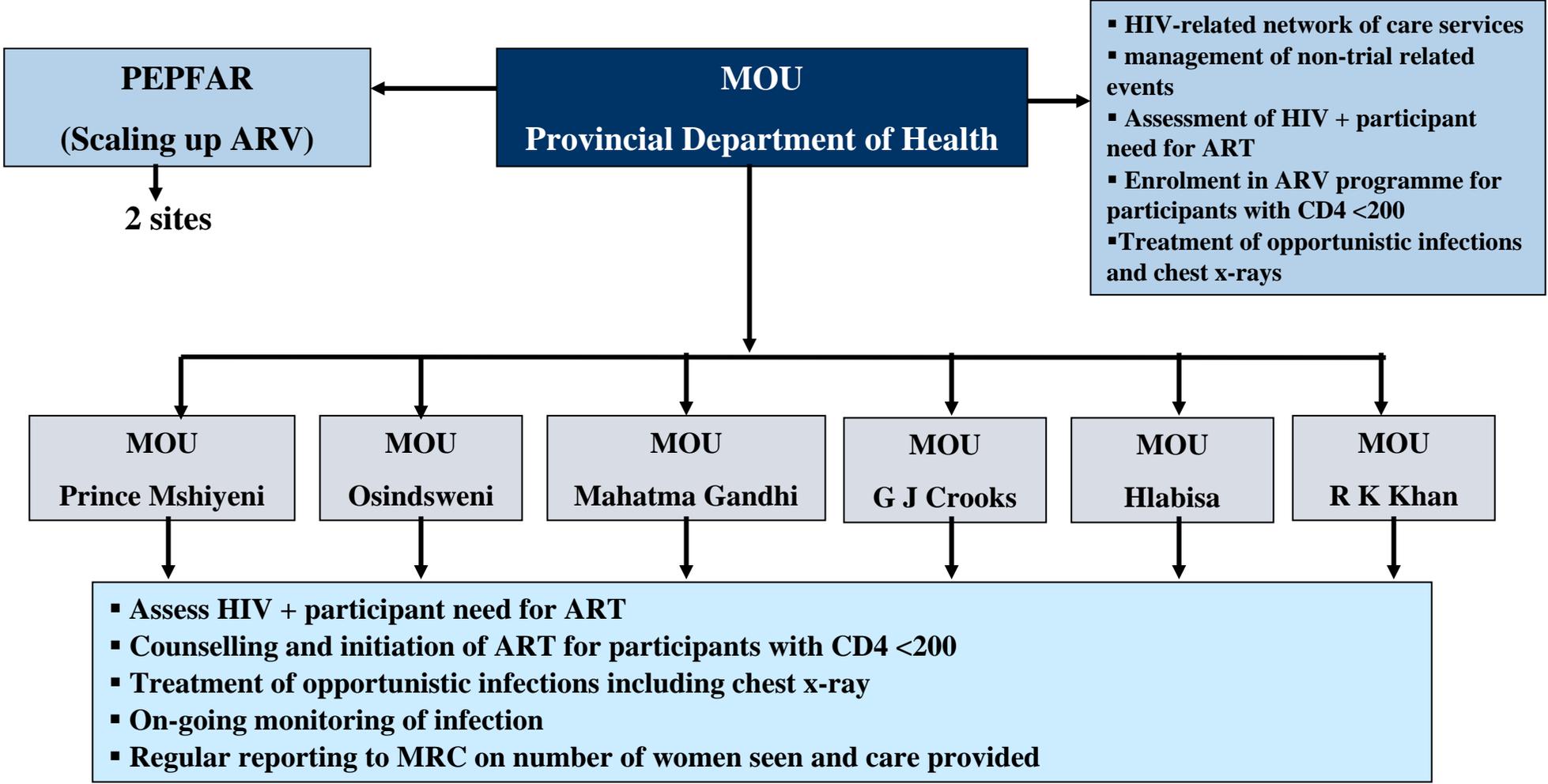
<b>Home language spoken (N = 1741)</b>	
English	90
Zulu	1271
Xhosa	9
Multi-lingual	137
<b>% Married</b>	23.47%
<b>Mean Age</b>	28.69 yrs
<b>Mean years of education</b>	9.10 yrs
<b>% Employed</b>	19.79%



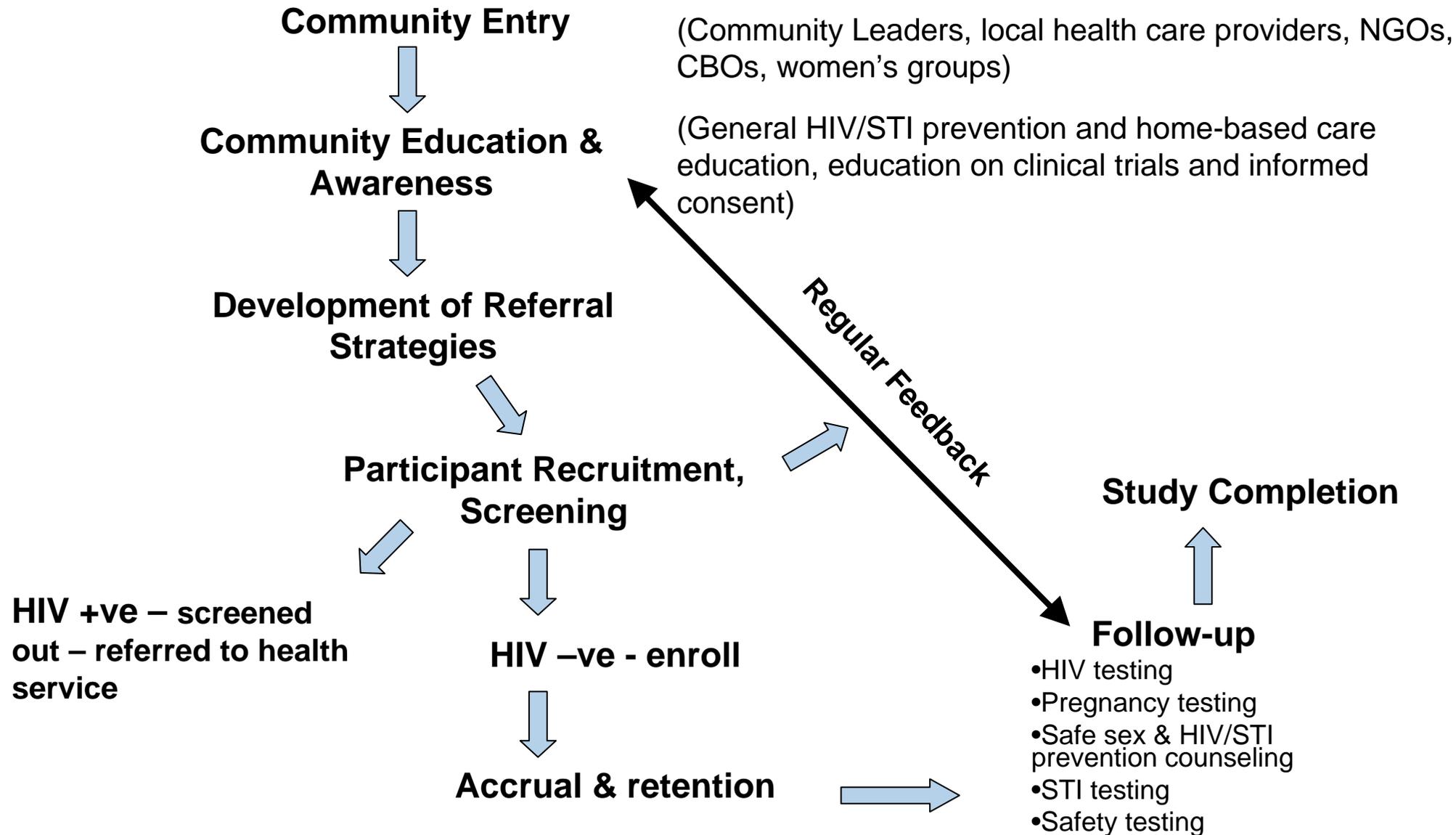
## HIV Prevalence and Incidence data from Chatsworth, Botha's Hill and Umkomaas

Clinical Research Site	Chatsworth	Umkomaas	Botha's Hill
Completion date	Mid 2008	Completed MIRA	Complete MIRA
HIV Prevalence (%) – Preparedness Study	Preparedness 37 (n=240)	43 (n=761)	43.5 (n=754)
HIV incidence cases (per 100 women years) – Preparedness Study	5.0/100wy	Estimated 6-6-8/100wy	Estimated 6-8/100wy





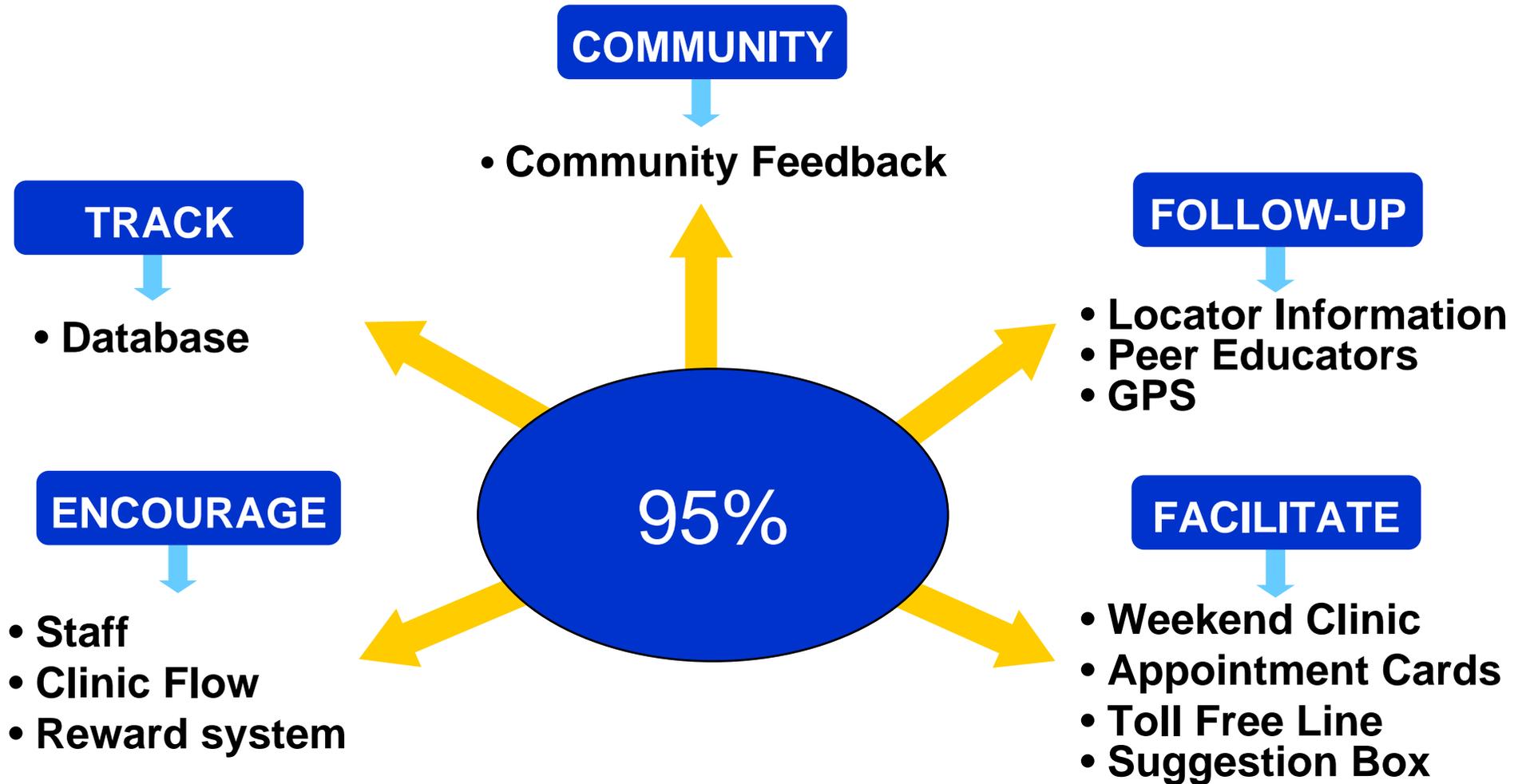
**NB: MOU to be set up prior to study initiation**



## **Community Support**



- **Participant accrual**
- **Peer education programme**
- **Regular community meeting attendance**
- **Door-to-door, NGO, CBO**
- **Referrals from partners**





## Major challenges with product and condom adherence

- ⚡ Disclosure of trial participation to partner
- ⚡ Women may not be happy with their randomisation assignment
- ⚡ Condom negotiation still a problem
- ⚡ Clear messaging around use of product with condoms

## Key lessons learned from previous trial experience in addressing adherence problems

- ⚡ Need for male partner involvement
- ⚡ Ascertain full understanding of product assignment before randomisation
- ⚡ Reiteration of adherence messages at every visit