

CAPRISA 004 CO-ENROLLMENT

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HIV Prevention Research Unit

**MTN Regional Meeting
Cape Town International Convention
Centre, South Africa
7 to 12 September 2008**



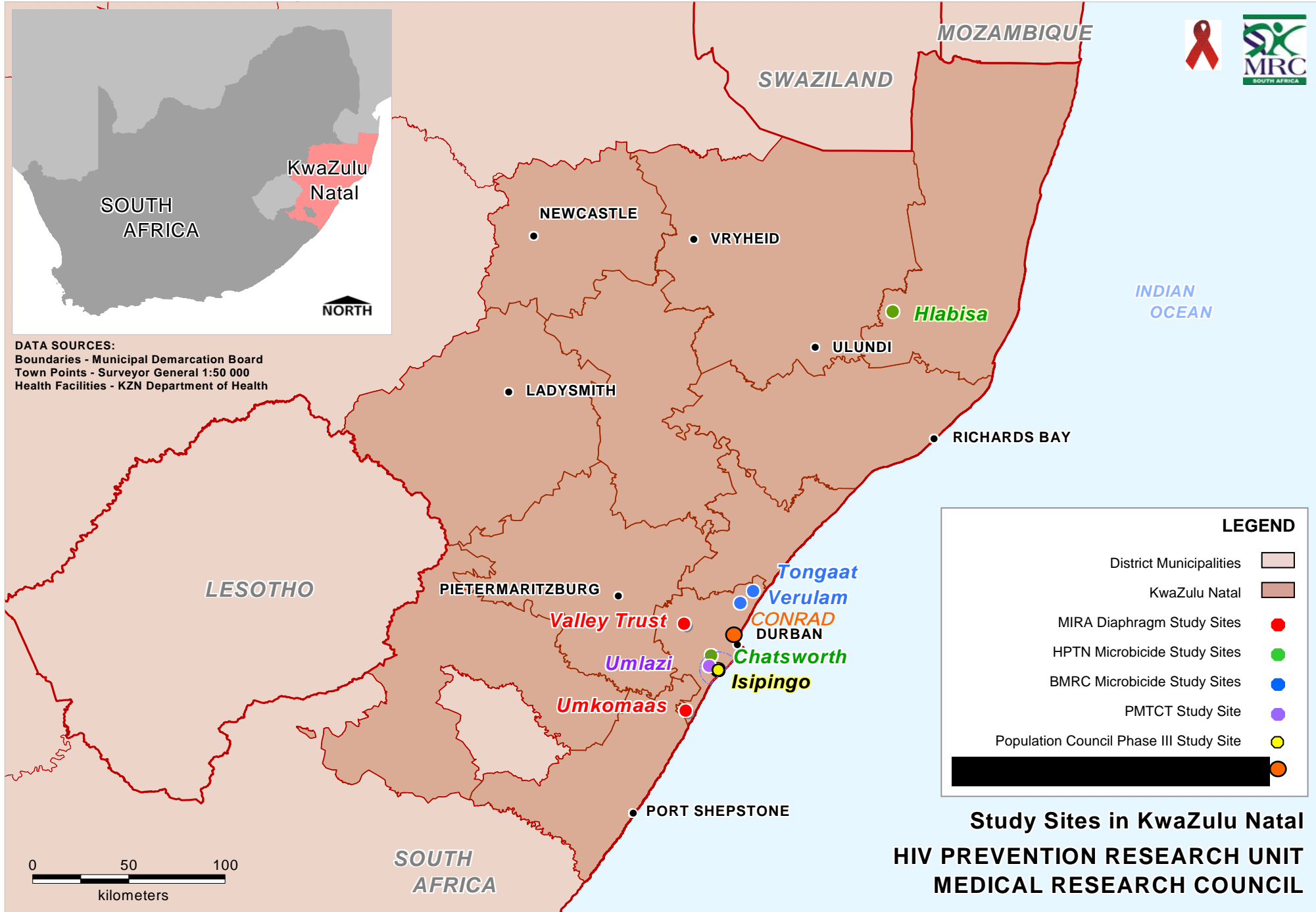
South African Medical Research Council

BUILDING A HEALTHY NATION THROUGH RESEARCH






DATA SOURCES:
Boundaries - Municipal Demarcation Board
Town Points - Surveyor General 1:50 000
Health Facilities - KZN Department of Health



LEGEND

District Municipalities	
KwaZulu Natal	
MIRA Diaphragm Study Sites	
HPTN Microbicide Study Sites	
BMRC Microbicide Study Sites	
PMTCT Study Site	
Population Council Phase III Study Site	



Study Sites in KwaZulu Natal
HIV PREVENTION RESEARCH UNIT
MEDICAL RESEARCH COUNCIL



- ⚡ In 2005 an excel database was used: HPRU-specific trials and sites**
- ⚡ 1 Workbook with 7 worksheets (1 per site) in the Durban area**
- ⚡ 1 Workbook with 2 worksheets (1 per institution: MRC and Africa Centre) in Hlabisa**
- ⚡ Very successful: 10 co-enrollments out of > 6000 participants across 9 sites and 5 trials (MIRA, HPTN 035, MDP301, Pop Council-Carraguard, CONRAD-Cellulose Sulphate)**



ENROLLMENT LOGS BY PARTICIPANT MENU



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Enrolled Logs - [Participants]

File Edit View Insert Format Records Tools Window Help

Type a question for help

MS Sans Serif 8 B I U

Enrolment Logs By Participant

for viewing only

Lookup by SA ID eg 6301255033088 (no spaces)

Lookup by Name eg Surname, First Names

Lookup by Date of Birth eg 1963/01/52

Study

Site

Surname

Firstname

SA Id

Date of Birth

Status

Comments

Enrolled Date

Screened Date

Exit Date

Record: 1 of 6514

Form View

Start HPRU-Enrolle... SOP for Co-e... Document1 - ... Inbox - Micro... Microsoft Exc... Menu : Form Participants 02:40 PM

ENROLLMENT LOGS BY PARTICIPANT MENU



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Enrolled Logs - [Participants]

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Enrolment Logs By Participant

Lookup by SA ID eg 6301255033088 (no spaces)

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Study

Site

Surname eg MANCI

Firstname eg James Lucas

SA Id eg 6301255033088 (no spaces)

Date of Birth eg 1963/01/52

Status

Comments

Enrolled Date eg 1963/01/52

Screened Date eg 1963/01/52

Exit Date eg 1963/01/52

First Entered

Last Modified

Last Modified By

Record: 1 of 1841

Form View

Start HPRU-Enrolle... SOP for Co-e... Document1 - ... Inbox - Micro... Microsoft Exc... Menu : Form Participants 02:41 PM

THE PROBLEM



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- 🚫 February 2008: 1st indication that there may be co-enrollments**
- 🚫 CAPRISA sent e-list of South African I.D. nos. to perform a retrospective check**
- 🚫 April 2008: full extent of problem uncovered**
- 🚫 Reported to DAIDS, Ethics, MCC and Department of Health.**
- 🚫 Participants called in and counseled**
- 🚫 Safety exams performed**
- 🚫 Elicited reasons for co-enrollment and daily reports sent to the DAIDS Medical Officer**

REASONS FOR CO-ENROLMENT



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	REASONS
	Money: Did not use the CAPRISA gel; concerned about safety
	Influences by other co-enrollers
	Money: Wanted to secure place in CAPRISA trial – didn't use CAPRISA gel
	Money: Did use the CAPRISA gel, wasn't concerned about safety
	Didn't realise that you couldn't co-enrol
	Wanted to make sure her HIV results were really negative
	Money: Using the reimbursement to pay for college
	Had no apparent reason for co-enrolling
	Knew of the dangers of co-enrolling

Based on the responses received

NEW DATABASE



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- ⓧ **Designed and implemented in May 2008**
- ⓧ **Access database with wireless connection**
- ⓧ **Uses South African Identity numbers and names (QC check to avoid mistyping of digits in identity number)**
- ⓧ **Linked to scanner to completely eliminate typing errors.**
- ⓧ **Targeted – for use by all research institutions in the Durban area**
- ⓧ **Currently in use by HPRU and CAPRISA**
- ⓧ **In discussions to include RHRU and IPM Investigators who will begin studies in mid 2009**
- ⓧ **Investigations into linking a fingerprint scanner to the database (to avoid I.D. fraud)**



CONCLUSION

- **The issue potential of co-enrollment identified in the Unit 2005- set up database system.**
- **Underestimated – participant reasons to enroll in multiple trials.**
- **Need for collaborations across all organizations involved in clinical trials – including treatment trials.**
- **Sharing of common participant database –approved by ethics- across all sites**
- **High reimbursement rate is an issue – recent communication with MRA- “we do NOT stipulate R150 for trial participation”- ?????????**



Conclusion

WAY FORWARD

- 1. Include information and concerns with co-enrollment in counseling scripts of all future trials.**
- 2. Counsel participants on co-enrollment at each follow-up visit and inform them that mechanisms are put in place for identifying co-enrollment**
- 3. Emphasize discussions on co-enrollment between recruitment staff and potential participants.**
- 4. Discuss co-enrollment at community entry and feed-back sessions.**