



INTERNATIONAL
PARTNERSHIP FOR
MICROBICIDES



The Ring Study: the road we travelled...

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On behalf of the IPM 027 Team

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1 October 2012, Cape Town, South Africa

IPM@10

A decade of progress advancing
HIV PREVENTION FOR WOMEN



The Ring Study

IPM 027

Protocol Version 1.0 Amendment 1.0 Dated 23 January 2012

**A MULTI-CENTRE, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED
SAFETY AND EFFICACY TRIAL OF A DAPIVIRINE VAGINAL MATRIX RING IN
HEALTHY HIV-NEGATIVE WOMEN**



The Ring Study

IPM 027

Protocol Version 1.0 Amendment 1.0 Dated 23 January 2012

Study design	Double-blind, Randomized (2:1), Placebo-controlled
IP	Vaginal rings inserted every 4 weeks \pm 7 days
Endpoints	Approx 80 endpoints; 2 year on IP
Power	83.2% power to detect 50% treatment effect
Targeted enrollment	1650 women, ages 18-45 1100 on Ring-004
Sites in Africa	5-6 IPM research center partners in 2-3 countries
Participant follow-up	2 years + 6 weeks following ring discontinuation

IPM 027 : Clinical Research Center Partners



Madibeng Center for Research
Brits, South Africa



Maternal, Adolescent and Child Health (MatCH)
Edendale South Africa



Qhakaza Mbokodo
Ladysmith, South Africa



Prevention of HIV/AIDS Project (PHIVA)
Pinetown, South Africa



Projet UBUZIMA
Kigali, Rwanda



Regulatory & IRB Approval Status

- **V1.0 (Long-term safety)**
 - MCC: Full approvals in South Africa 02 Nov 2011 for 4 research centres
 - Ethics/District: All approvals by Jan '12
- **V1.0, Amendment 1 (Long-term safety and efficacy)**
 - MCC, South Africa submitted 26 Jan `12, final approval 05 June '12 & Ethics/District approvals by Mar '12
 - Rwanda submitted 28 Feb `12, final approval 06 July '12
 - *Malawi submitted to COMREC 20 Mar `12 - Pending*



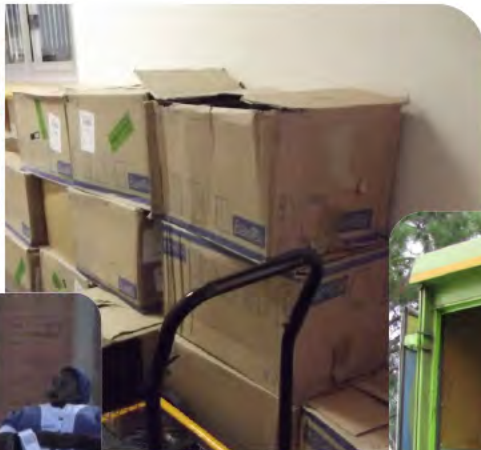
IPM 027: Timelines

- Investigator Meeting: 14-16 Feb '12
- SIVs: 19-29 Mar `12
- IXRS activated: 23 Mar `12
- 1st SA Participant Screened: 27 Mar `12
- IP at SA Research Center: 10 Apr `12
- 1st SA Participant Enrolled: 11 Apr `12

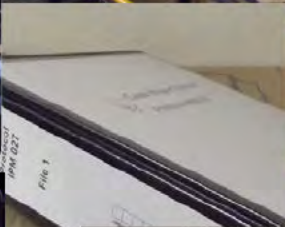
- Rwanda SIV: 21-24 Aug '12
estimated FPI Nov '12
- Estimated LPI: Q1/2 `13
- Estimated LPO: Q2 `15



SIVs



QM 19-20 Mar '12



PU 20-23 Aug '12



MCR 22-23 Mar '12

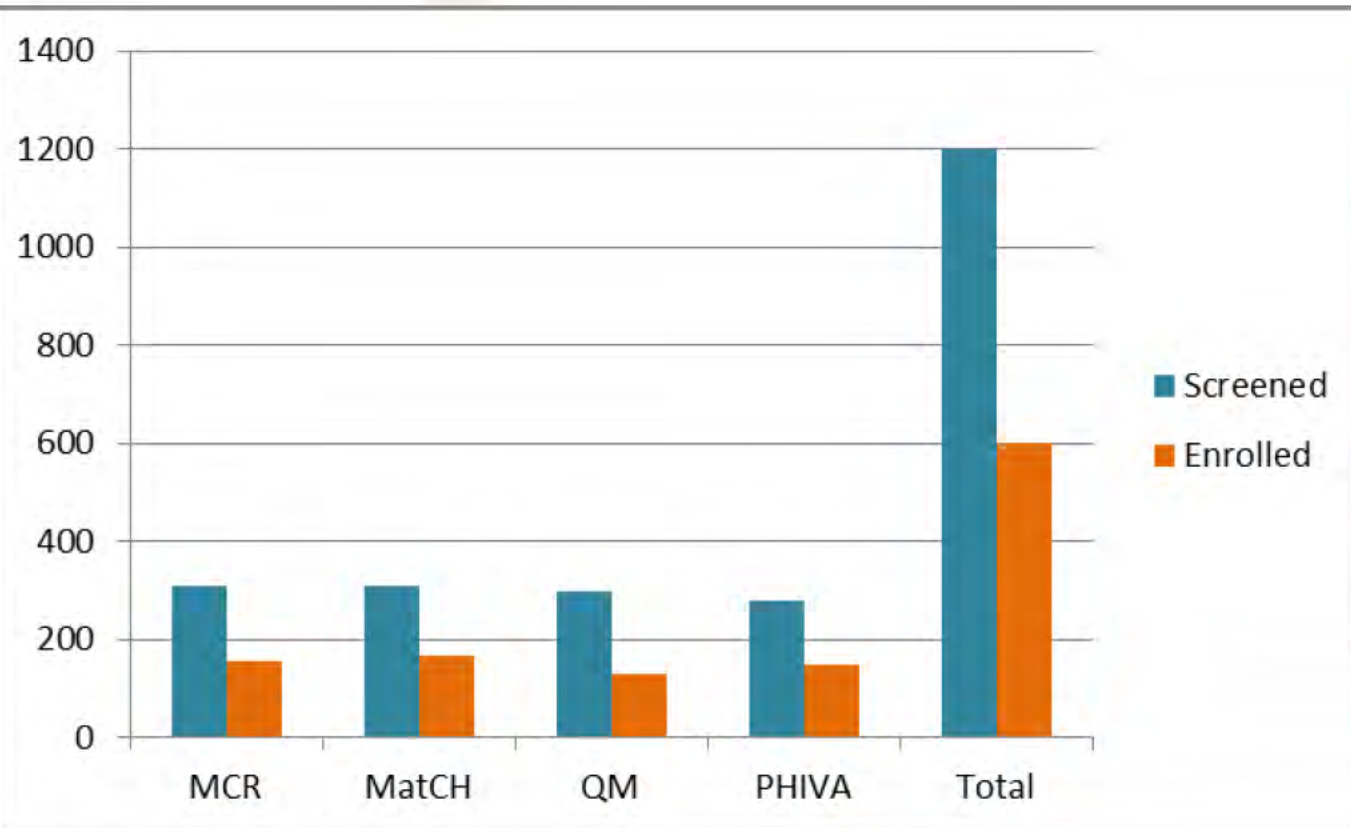


MatCH 26-27 Mar '12



PHIVA 28-29 Mar '12

IPM 027: Screening & Enrollment



	Screened	Enrolled
MCR	318	162
MatCH	318	175
QM	311	134
PHIVA	285	153
Projet Ubuzima	Expected FPI Nov '12	
Total	1232	624

As of 27 September 2012

Screen Failures

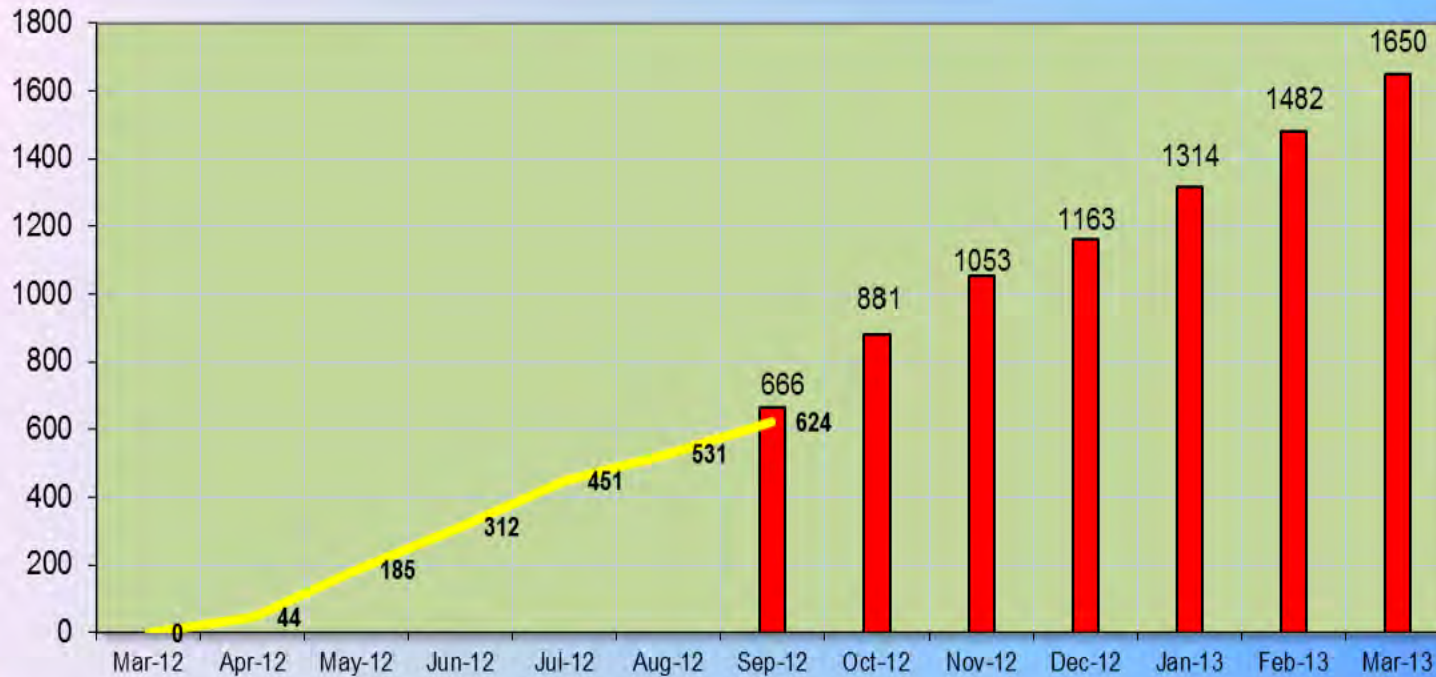
- HIV positive at Screening
- Unstable form of Contraception
- Cervical Cytology Abnormalities
- Symptomatic for Genital Infections
- Grade 2 or higher abnormal lab values
- Investigator Opinion

Early Discontinuations

- Relocation out of district
- Partner Pressure
- Withdrew of informed consent
- Medical reasons



Accumulative Participant Enrollment/Month

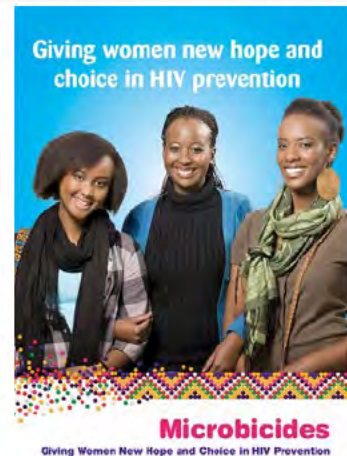


■ IPM 027 Revised Cumulative Monthly Forecast
— IPM 027 Revised Cumulative Actual Enrolment

27 September 2012

Upscaling....

- Infrastructure & Equipment
- Optimization of resources & space allocation
- Revisit clinic flow
- Research staff composition
- Increase community mobilisation & innovative recruitment



.....weeks to come

- Focus on Retention
- Re-align Recruitment Strategy
- Environmental Factors
- Operational Challenges
- Male Partner Involvement
- Dispense Family Planning
- Per Participant strategy for relocation out of the area
- Proactive planning for festive season...



Months to come.....

- Getting to 1650
- Data Quality is Important
- Cost-Efficiency Matters
- Adherence is Key
- Retention is Adherence
- Plan for Success

***Ordinary people can
achieve
Extraordinary things
as a TEAM***

