



INTERNATIONAL
PARTNERSHIP FOR
MICROBICIDES

From Ring to DREAM

Mariëtte Malherbe – IPM, Clinical Support Manager

MTN Regional Meeting – Plenary Meeting

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Overview From Ring to DREAM

- Women's Vulnerability to HIV
- Women Need Multiple Options
- Dapivirine Vaginal Ring
 - The Ring Study Status
 - DREAM Status

The Regulatory Pathway for The Ring

- Regulatory Pathway
- Next Steps for Dapivirine Vaginal Ring
- Future Prospects
- Conclusion

Women's "Vulnerability" to HIV



Gender inequities, including gender-based and intimate partner violence

- Condom use can be difficult to negotiate
- Financial dependence on male partners



Young women at higher risk

- Early marriage, intergenerational sex and concurrent partnerships
- Limited access to SRH information and health services



Higher male-to-female transmission

No ONE OPTION WILL SATISFY ALL WOMEN

Women-initiated technologies

- a key component of a comprehensive prevention package

New and multiple mechanisms of action

- could help reduce chance of acquiring drug-resistant HIV



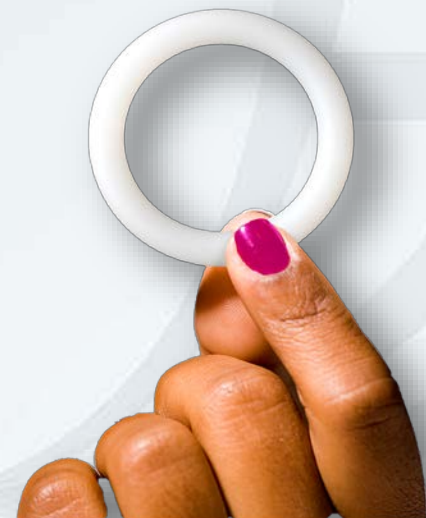
Dapivirine Vaginal Ring

Dapivirine

- Dapivirine licensed to IPM in 2004 from Janssen Sciences Ireland UC; expanded to exclusive worldwide rights in 2014
- NNRTI blocks ability of HIV-1 to replicate inside healthy cells

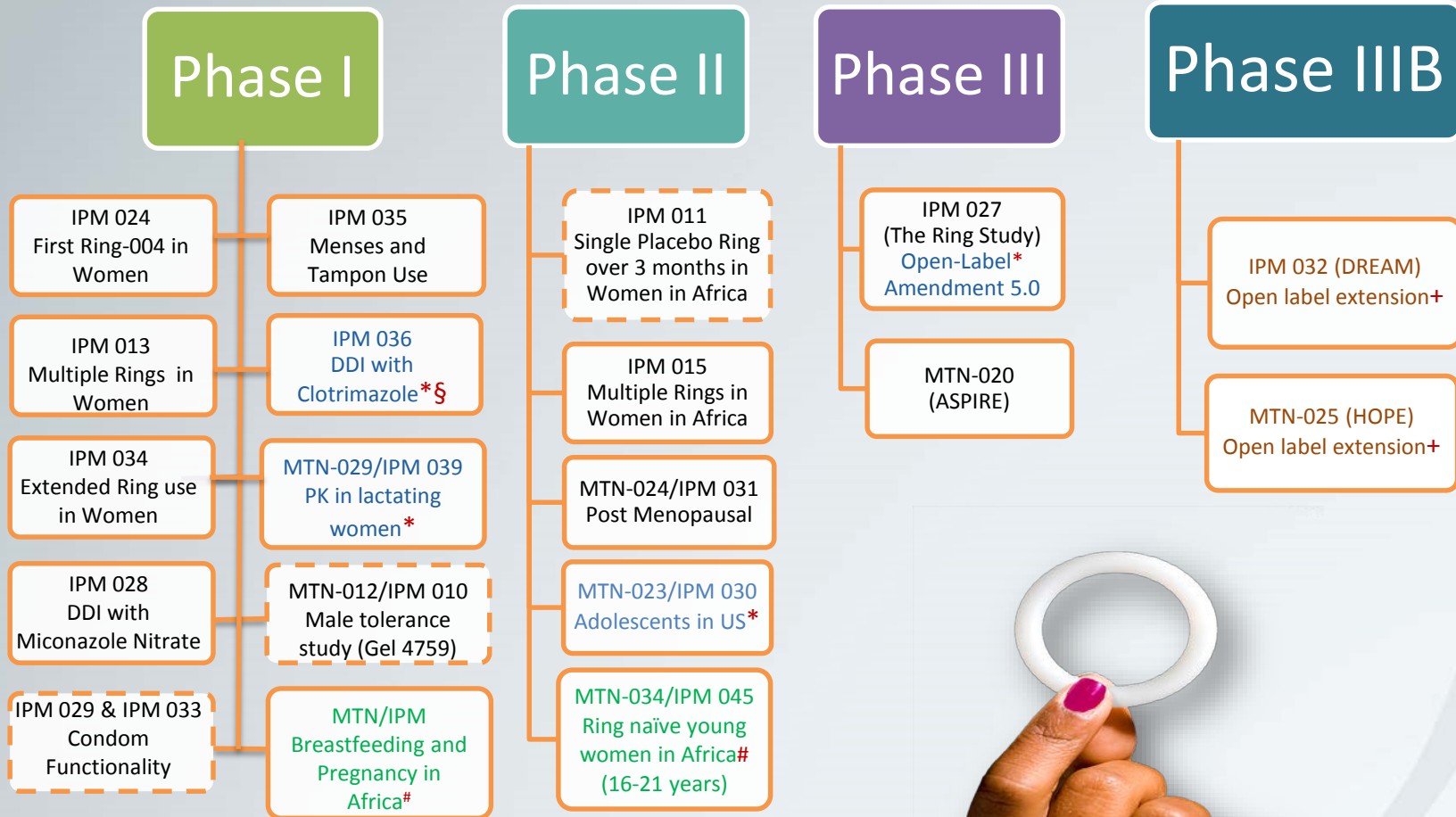
Dapivirine Vaginal Ring

- IPM regulatory sponsor
- IPM developed and manufactured the first dapivirine ring
 - Flexible silicone matrix ring
 - Long-acting: self-inserted every 4 weeks
 - Slowly releases drug into vaginal tissue
 - Acceptable to women and their male partners



Clinical Development Plan

Dapivirine Vaginal Ring-004



*In analysis

+Ongoing

#Planned


§ Additional arm, measuring PK levels with intermittent ring use



Ring to DREAM


IPM 027: The Ring Study

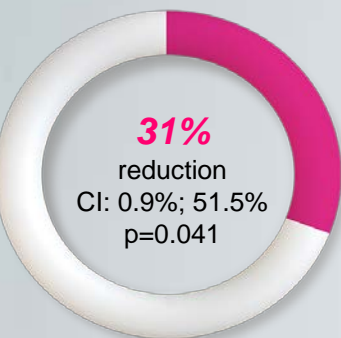
A MULTI-CENTRE, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED SAFETY AND EFFICACY TRIAL OF A DAPIVIRINE VAGINAL MATRIX RING IN HEALTHY HIV-NEGATIVE WOMEN

	IPM 027		
	Screened	Enrolled	Completed
South Africa and Uganda*: <ul style="list-style-type: none"> 7 Research Centres 	3425	1959	1161

IPM 032: DREAM

A FOLLOW-ON, OPEN-LABEL TRIAL TO ASSESS CONTINUED SAFETY OF AND ADHERENCE TO THE DAPIVIRINE (25 mg) VAGINAL RING-004 IN HEALTHY, HIV-NEGATIVE WOMEN

	IPM 027 (n=1959)	IPM 032		
	Eligible	Screened	Enrolled	Ongoing
South Africa and Uganda*: <ul style="list-style-type: none"> 6 Research Centres 	1731 at 7 RCs	1002	893	853



- 77 out of 1300 women acquired HIV-1 in dapivirine ring group
4.1% HIV-1 incidence/100 PY
- 56 out of 650 women acquired HIV-1 in placebo ring group
6.1% HIV-1 incidence/100 PY

Role over visits lessons learned

150 participants
rolled over
directly from
The Ring Study to
DREAM

- ❖ Not to repeat visit procedures
- ❖ Not to repeat samples
- ❖ Correctly label samples for the corresponding protocol
- ❖ Complete correct procedures per protocol
- ❖ Engage with staff to ensure that DREAM is seen as a new protocol and not an extension of The Ring Study

Screening Failures:

Main Reasons

- Positive HIV Status
- Unavailable for all visits
- Currently pregnant, intends to become pregnant or breast-feeding
- Contraception non-use

Declining Trial Participation:

Main Reasons

- Family influences
- Working / School / Studies
- Planning a family / getting married
- Relocation
- Not interested



Retention



Retention: 90.4%



Retention: 99.5%

Approximately 10 months after start up

Value of Adherence Events

- Sexual and reproductive health discussions are very important to women
- Received feedback from participants on topics they want to engage on - this differs between age groups
- Girl talk facilitates discussion on issues affecting them directly
- Participants enjoy facilitating their own events (take ownership)
- Participants enjoy events held outside of research centre e.g. in a park
 - Informal discussions make it easy for participants to interact especially in an informal setting

Value of Male engagement events

Male engagement is not an activity, but a process



- Prefer to be engaged in their own space
 - Males are more engaged through informal activities such as sport, at a tavern and or car wash spots
- To be engaged on what their female counterparts are doing, especially issues concerning sex and sexual reproductive health
- Improved relations with other male formations such as, Brothers for Life, Men's Sector, One Men Can, etc.

Adherence Messages

*“Support the Ring,
support future
generations”
(MRC/UVRI)*

*“If you love her
ring her”
(Ndlovu)*

*“With women
supporting each
other incredible
things happen”
(MatCH)*

*“Ring for all
occasions” (MCR)*

*“Developing the
heritage of an HIV free
future generation for
women through the
Dapivirine Ring”
(QM)*

*“Springing into
Spring with the
Ring”
(DTHF)*



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