

IPM 027 Current Status

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ASPIRE Team Meeting
MTN Regional Meeting
Westin Cape Town Hotel, Cape Town South Africa
04 October 2014





Two Studies, One Product

The Ring Study

Objectives

Long-term Safety and Efficacy

Study design

Double-blind, Randomized (2:1), Placebo-controlled

Investigational product

Vaginal rings inserted every 4 weeks \pm 7 days

Power

81% power to detect 50% treatment effect

Targeted enrollment

1950 women, ages 18-45

1300 on Ring-004

Sites in Africa

7 IPM research center partners in 2 countries

Participant follow-up

2 years + 6 weeks following ring discontinuation

The Ring Study: timelines



Madibeng Center for Research

Brits, South Africa



Maternal, Adolescent and Child Health
Department of Obstetrics and Gynaecology
University of the Witwatersrand

Maternal, Adolescent and Child Health (MatCH)

Edendale, South Africa



PHIVA

Prevention of HIV/AIDS Project (PHIVA)

Pinetown, South Africa



Qhakaza Mbokodo

Ladysmith, South Africa



DESMOND TUTU
HIV FOUNDATION

Desmond Tutu HIV Foundation (DTHF)

Masiphumelele, South Africa

MRC MRC/UVRI Uganda
Research Unit on AIDS

Uganda Virus Research Institute (UVRI)

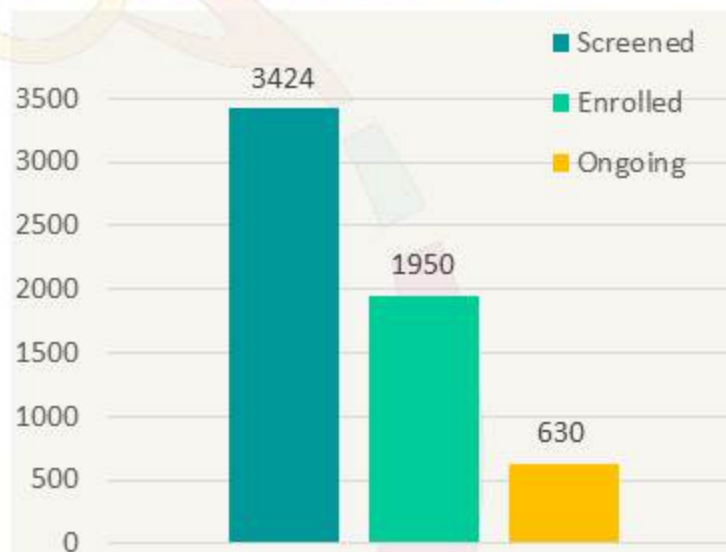
Masaka, Uganda

NDLOVU
CARE GROUP



Ndlovu Care Group

Groblersdal, Limpopo, South Africa



First
Participant
Enrolled

Apr '12

Last
Participant
Enrolled

Nov '14

Final Visit

Dec '16



The Ring Study: key priorities

Adherence:

- 25% Participants still active → significant impact

Retention

- 97% for ongoing participants → significant impact

Clinical and Laboratory Safety

- No safety concerns or laboratory disconcerts

Data Quality

- 99% clean database
- Real time data entry & cleaning

Inspection Readiness

- Ready at any time

Two Studies, Different Timelines

Both studies started enrolling in 2012, but are designed differently:

ASPIRE

- Followed participants for minimum 1 year
- Study completed June 2015
- ASPIRE results expected early 2016

The Ring Study



Following participants for 2 years for long-term safety

Completion December 2016 after last participant completes safety follow-up

Ring Study efficacy results scheduled for early 2017

- Possibly 2016 pending DSMB recommendation





IPM 027: Results Scenarios pending ASPIRE Results

SAFETY + EFFICACY

DSMB recommends –

- Amend Ring Study to Open-label and/or Initiate DREAM study
- Submit dossier for regulatory approval
- Consult Regulators*

CONTINUE AS PLANNED

DSMB recommends –

- Study continue as planned to ensure robust results and provide comprehensive data on the ring's efficacy and long-term safety
- Consult Regulators*

SAFETY + INSUFFICIENT EFFICACY

DSMB recommends -

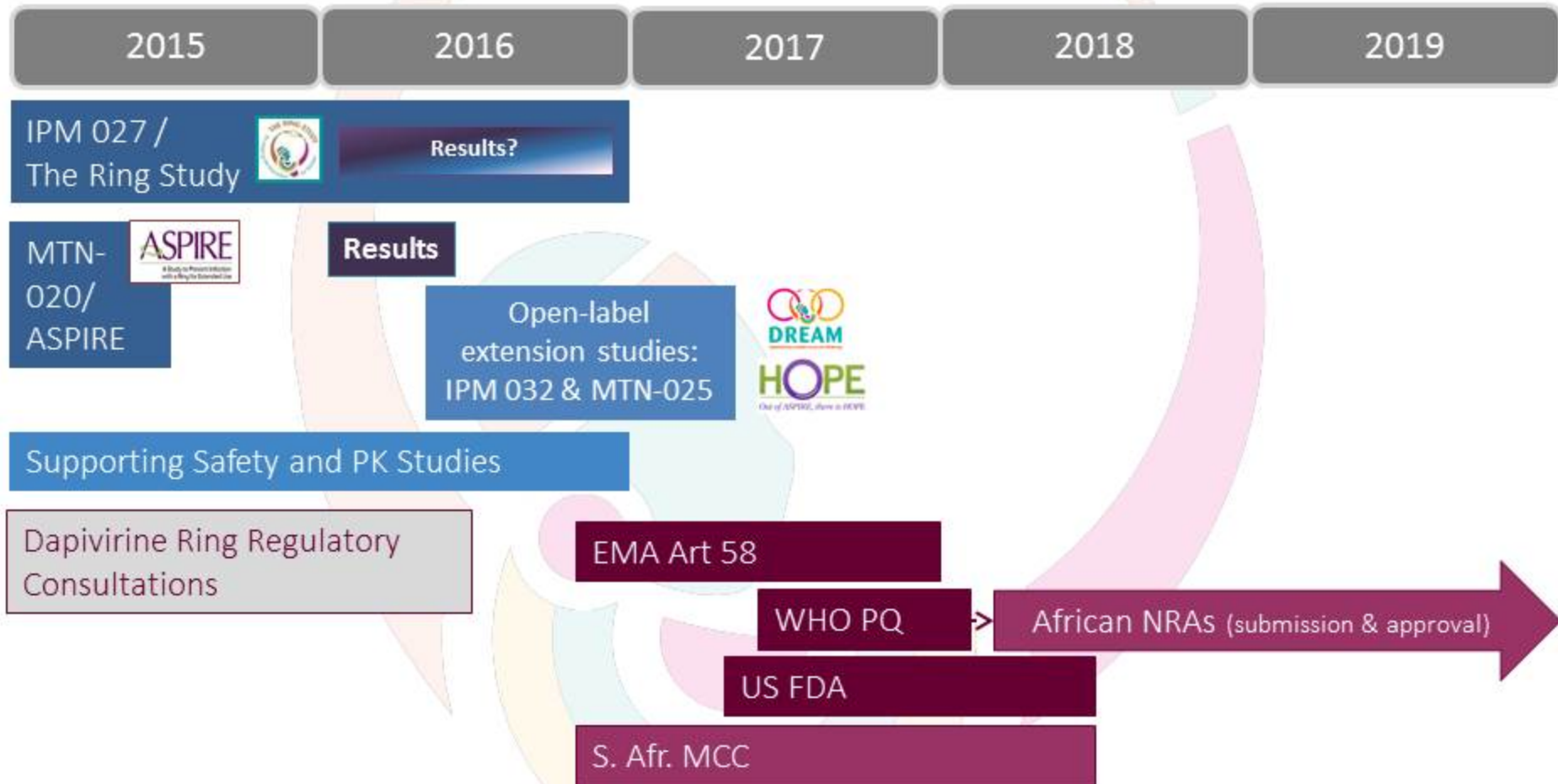
- Stop The Ring Study
- Terminate dapivirine ring program
- Results show the dapivirine ring is safe but not efficacious or has limited efficacy
- Consult Regulators*

IPM 032: Open-Label Ring Follow-on

DREAM	Dapivirine ring Extended Access and Monitoring
Primary Objectives	Long-term Safety and Adherence
Design	Follow on IPM 027; Open-Label
Treatment Follow-up Regimen	Vaginal rings inserted monthly 1-monthly (no additional rings) 3-monthly (optional: 2 additional rings)
Targeted enrollment	Approximately 1400 women
Product use period	Approx. 1-year follow-up with option to extend
Expected start	Pending outcome Phase III trials



Regulatory preparation is real time



The Ring Study

Adherence is Still Everything

- The Ring Study participants are still ongoing
- Keep focus on retention and adherence
- Results of The Ring Study are scheduled early 2017
 - Available sooner pending ASPIRE results and IPM DSMB recommendation
- If both Phase III studies find the dapivirine ring safe and effective, it would be a pivotal moment for the future of microbicides

Acknowledgements

- Participants
- Research Centre Teams
- Community Members and Stakeholders
- MTN / NIH / DAIDS colleagues
- Vendors and Partners
- IPM Colleagues and Friends
- Donors

It takes a village to raise the child: Dapivirine Ring-004





We are closer to making the Dapivirine Ring-004
an important new HIV prevention option for Women

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GATES foundation**



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International
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ASPIRE

A Study to Prevent Infection
with a Ring for Extended Use

Thank you for your contribution.....

