



# MTN State of the Network

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**Sharon Hillier and Jared Baeten**  
**September 19, 2017**

Cape Town, South Africa

# Where we are and where we are going.....

- The danivirine ring is moving through



own

- Tremendous work ongoing in MTN Core, SCHARP and at IPM
- We must celebrate this progress toward licensure!

# Stay Tuned.....

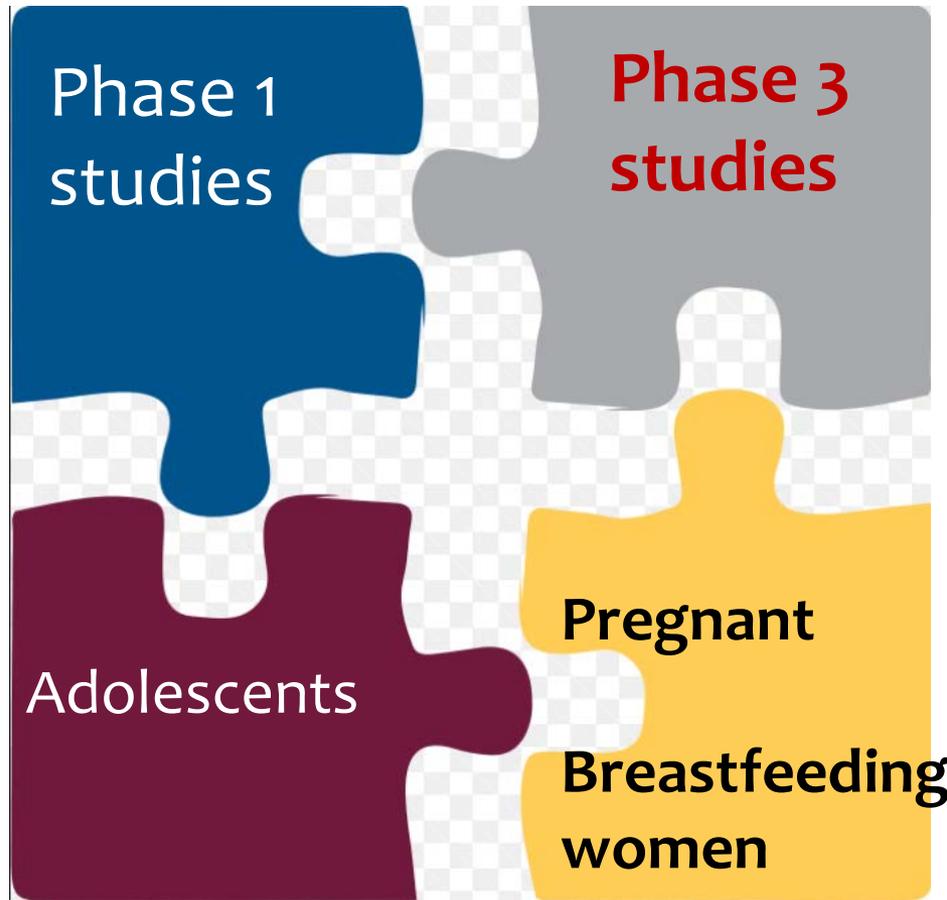
- You will be hearing all about DREAM, the open label extension study from The Ring Study and the regulatory pathway for the ring from our colleagues at IPM later this morning

# From ASPIRE to HOPE

- Nearly 1400 women enrolled in HOPE
- More than 95% retention.
- Lots of lessons learned
  - Enrolling women in an open label extension study is surprisingly complex. (Brenda Gati, today)
  - We can be more efficient with our visits (Nyaradzo Mgodzi, today)
  - Women have lots of reasons they decide or do not decide to participate (Chifundo Zimba, Thursday) and have lots to tell us about it (Krina Reddy today)
  - COACH counseling in HOPE has been challenging and rewarding (Thursday AM)



# Filling in the Pieces of the Puzzle for Dapivirine Ring



This morning:  
Katie Bunge-  
MTN-023

REACH study  
Lulu Nair

Wednesday  
morning:

- Renee Heffron-  
Why we need  
to study the  
ring in  
pregnancy

- Lisa Noguchi  
MTN-029 study

# What Are We Learning from Young Women- two initiatives

Stakeholder consultations with young women from Kenya, South Africa, Zimbabwe and Uganda



End user input from women from South African communities not in our studies: Routes to Results

# Input from Stakeholder Consultations

- Need to have prevention products that look less “medicalized,” more like cosmetics and less like something for sick people
- Like the REACH study approach of providing CHOICE of products after trying both.
- Young women want to have products that do more (prevent against pregnancy and other STIs) and last longer
- Empowered: excited about having more control over their own health

# Key Messages from 18-21 Year Old Women in South Africa

- Young women are excited about the opportunity to use HIV prevention products- this is empowering.
- There is a need for more **community** support for HIV prevention.
- The ring is NEW and unfamiliar and causes anxieties when women first see it.
- Some want the ring, some want oral PrEP, some are not interested in either

# Dapivirine Ring Pregnancy and Breastfeeding Studies

- MTN-029/IPM 039 - Phase 1 Pharmacokinetic Study of the Dapivirine Vaginal Ring in Lactating Women
- Three studies in development:
  - 4 sites: Malawi, Uganda, South Africa and Zimbabwe
  - MTN-041 – Qualitative Assessment of Acceptability of a Dapivirine Vaginal Ring and Oral FTC/TDF Use During Pregnancy and Breastfeeding (Q1 2018)
  - MTN-042 – Randomized, Open Label Safety and Pharmacokinetic Trial of Dapivirine Vaginal Ring and Oral FTC/TDF Use in Pregnancy
  - MTN-043 – Open Label, Pharmacokinetic, Month-Infant Pair Study of Dapivirine Ring Use in Breastfeeding

# What Else is in the Pipeline?



- Rings that could protect against HIV for 90 days
  - MTN-036: study of the 90 day dapivirine ring in US women: set to launch in the US later this year
  - MTN-038: study of the 90 day tenofovir ring; phase 1 study protocol under development
- MPT rings
  - MTN-030: Dapivirine ring containing levonorgestrol – stay tuned for Sharon Achilles on Wednesday
  - CONRAD MPT ring studies ongoing

# Dapivirine ring: thinking beyond HOPE

| Efficacy in clinical trial                      | Effectiveness in open-label study                             |
|---|---|
| 44%<br>(33% among those <25 years old)<br>iPrEx | 86%<br>PROUD  |
| 75%<br>Partners PrEP Study                      | 95% (historical comparison)<br>Partners Demonstration Project |

# PROUD

- Among MSM in the UK, access to PrEP, in the context of other prevention services, was compared to deferred access to PrEP:
  - Immediate PrEP = 3 infections, incidence 1.2%/year
  - Deferred PrEP = 20 infections, incidence 9.0%/year
  - 86% effectiveness, NNT = 13



# Rationale for a PROUD-like study

- The dapivirine vaginal ring has been demonstrated to be efficacious and safe for HIV prevention, but knowing its effectiveness in real-world settings is key.
- A potential next study for the ring is PROUD-like study that would evaluate impact in real-world settings...
  - Stay tuned – great opportunity.



# The Rectal Microbicide Road Ahead Wednesday AM!

- MTN Rectal Microbicide Agenda:
  - 7 drugs & 4 formulations being tested
  - 5 MTN RM studies under development, 2 expected to launch before the year end
- New MTN sites for RM research in South Africa and Blantyre
  - See Noel Kayange from Blantyre on Wednesday AM



# HIV Prevention Landscape

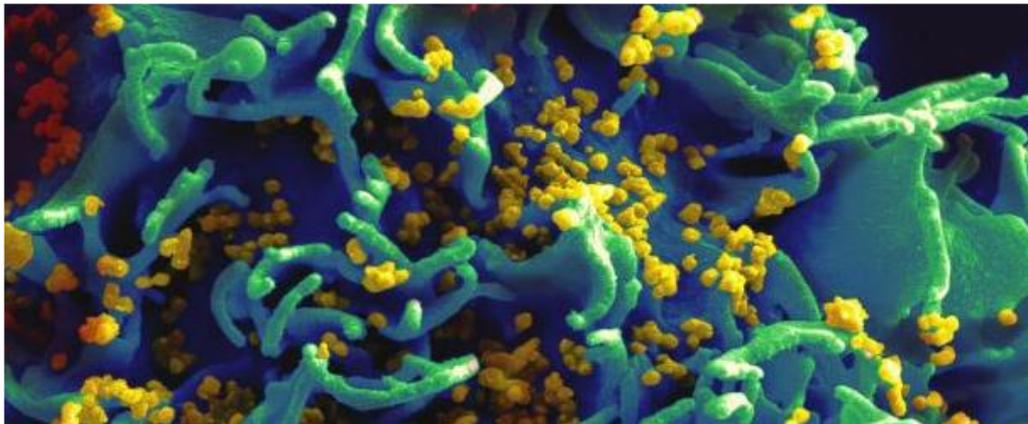
- Truvada as oral PrEP is rolling out everywhere
  - Updates from the Pills Plus Project in Cape Town, PrEP rollout in Kenya and South Africa on Wednesday morning.
  - Availability of PrEP is changing views on placebo controlled trials
- Next generation injectable PrEP (cabotegravir) in clinical trials and implantable PrEP in development
- Is there still a role for topical microbicides?

# Planning for the Future is NOW!



Tuesday, September 12, 2017

## NIH HIV/AIDS Network Refinement Update: Focusing the Science-Driven HIV Research Enterprise



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Every 7 years, NIH competitively renews its funding of the HIV/AIDS clinical research networks operating in the United States and internationally. In a [new blog post](#), NIAID Division of AIDS Director Dr. Carl Dieffenbach describes how NIH can most effectively refine the HIV research enterprise to hasten an end to the pandemic. The NIH HIV research agenda is grounded in three

# From Carl Dieffenbach.....

- We have effective prevention tools: daily oral PrEP), PEP, voluntary medical male circumcision, and a dapivirine vaginal ring.
- Criteria for future development:
  - safe, desired and highly effective
  - **should provide systemic protection irrespective of route of exposure** (long-acting injectables, implantables and sustained-release oral formulations)

# Is there still room for topical microbicides?

- How important is choice?
- Will everyone who needs prevention be willing to choose to be on a systemic ARV or antibody?
- Is there a role for products like the ring which can only protect women from vaginal sex?
- Is there a role for on-demand products for women and men? And MPTs?
- Will we end the HIV epidemic with the tools we have now?

# Please Share Your Views with DAIDS

- You can send your comments directly by email to

[NIAIDnetworkrefinement@mail.nih.gov](mailto:NIAIDnetworkrefinement@mail.nih.gov)

- Or through this link:

<https://www.niaid.nih.gov/forms/refining-hiv-research-enterprise-response-form>

# What are the Strengths We Have in the MTN which Can Contribute to Ending the Epidemic?

- Focused scientific agenda, protocol development & implementation
- Strong relationships with sites.
- Focus on **adolescents** and pregnant and breastfeeding women.
- Willing to incorporate lessons learned from the previous protocol into the next one.

# What are the Strengths We Have in the MTN which Can Contribute to Ending the Epidemic?

- Strong engagement with the participants and stakeholder communities.
- Expertise with experimental products and the regulatory issues associated with such products.
- Integration of biomedical and behavioral expertise from mucosal immunology to end user perspectives.
- We have contributed to bringing a new product forward to licensure.

# Looking Toward the Future

- Your feedback is essential!
  - share your thoughts with NIH regarding the future of prevention.
  - This is an expectation, not a request!

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Celebrate