

# Welcome and State of the Network

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Cape Town,  
South Africa  
October 6<sup>th</sup> 2015

# HIV & AIDS in Africa

- In 2013
  - 24.7M living with HIV
    - 58% women
  - 1.5 M new infections (4,109 per day)
    - 33% reduction from 2005
  - 1.1 M deaths (3,013 per day)
    - 33% reduction from 2005
- By March 2015
  - Global ART coverage 41%

# HIV Prevention in 2014/2015

- More evidence for PrEP effectiveness in MSM
  - Proud study (UK) & IperGay (France)
- Exciting Long Acting (LA) PrEP non human primate data
- Preliminary data on broadly neutralizing antibodies (bNab)
- Phase 1 studies of LA PrEP and bNabs completed and Phase 2 studies ongoing

# Oral PrEP

- PrEP Trials in European MSM
  - PROUD (86% reduction)
  - IperGay (86% reduction)
- PrEP Demonstration Projects

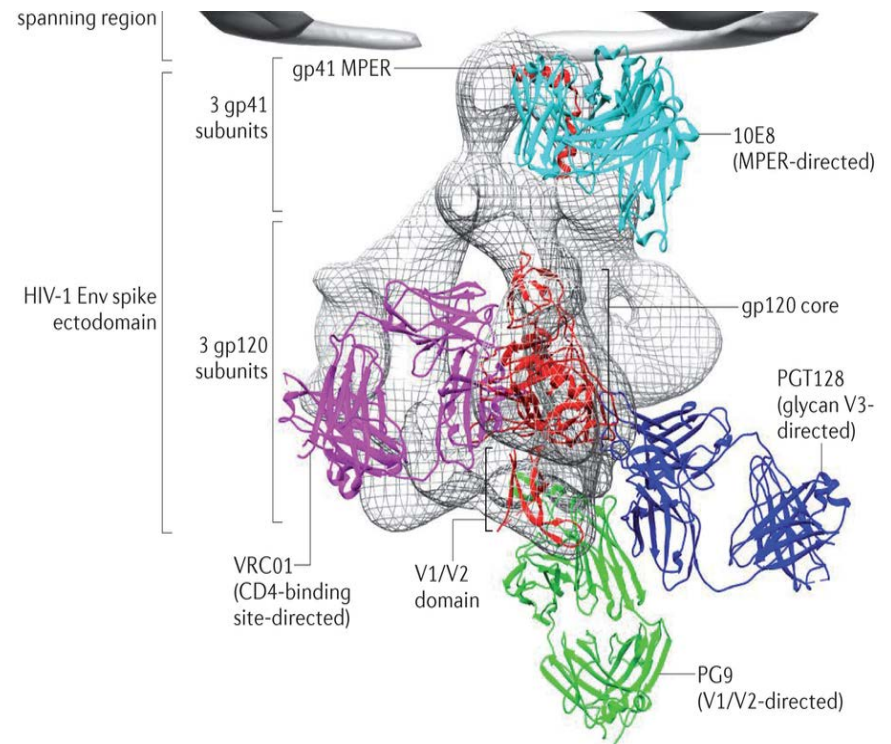
Partners	Kenya & Uganda	Serodiscordant couples
AMPrEP	Netherlands	MSM & TGW
PRELUDE	Australia	High risk men and women
PrEPBrasil	Brasil	MSM & TGW
CHAMPS	South Africa	Heterosexual adolescents

# New PrEP Approaches

- LA PrEP Agents
  - Rilpivirine (HPTN-076)
  - Cabotegravir (HPTN-077 and HPTN-083)



- Broadly Neutralizing antibodies (HPTN-081)



# What Makes for a Successful HIV Prevention Strategy?

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# The Prevention Score Card

	Clinical Trials	Implementation			Adherence
	Safety & Effectiveness	Cost	Medical Monitoring	Burden	
Oral PrEP	+++ / +++	\$\$	++	++	+++
LA PrEP	++ / ?	\$\$\$	+++	+++	0
Antibodies	++ / ?	\$\$\$\$	++++	++++	0
Vaccines	++ / +	\$\$	++	+	0
Microbicide gels	+++ / +	\$\$	++	++	+++
Intravaginal rings	+++ / ?	\$	+	+	++
Circumcision	+++ / +++	\$	0	0	0

# Prevention Priorities

- The prevention toolbox is real and like contraception provides choices
- All current HIV prevention strategies have strengths and weaknesses
- We have learned that the dapivirine IVR is safe, acceptable, and used
- Effectiveness data awaits, but the ring appears to be an attractive option with respect to scale up and implementation







# MTN Activities in 2014/2015

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# MTN Trials Completed in 2015

- MTN-017
  - Phase 2 rectal safety and acceptability study
- MTN-011 study
  - PK/PD coital study of TFV gel
- MTN-014 study
  - Rectal/vaginal safety and PK study of RGTFV gel
- MTN-020 (ASPIRE) study
  - Phase 3 evaluation of the DPV IVR
- MTN-024
  - Phase 2a safety study of the DPV IVR in post menopausal women

# New/Ongoing MTN Trials

- New Populations for the dapivirine ring:
  - MTN-023: Phase 2a safety study of a DPV IVR in adolescent females
  - MTN-029: Phase 1 PK study of the DPV IVR in lactating women
- New agents for use as rectal microbicides:
  - MTN-026: Phase 1 rectal safety and PK study of DPV Gel
- New classes of drugs formulated as rings:
  - MTN-027: Phase 1 safety and PK study of MK-2048/Vicriviroc (MK-4176)/MK 2048A IVR
  - MTN-028: Phase 1 PK study of IVR containing Vicriviroc (MK-4176) and MK-2048

# Contributions in Reproductive Health

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- Contraceptive Action Team:
  - Diversified the contraceptives used at all of our ASPIRE sites
  - Built capacity in staff to become experts in family planning, including insertion of IUCDs, implants
  - Met the goal of decreasing reliance on DMPA and ensuring that no more than 50% of women enrolled in ASPIRE at any site used any single contraceptive

# Opportunities & Challenges

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# Opportunities for the MTN

- Building on the foundation of the ASPIRE trial
  - The HOPE study
  - DPV IVR studies in African adolescents (MTN-034)
- Moving towards a three month DPV IVR
- Further development of second generation IVRs
- Evaluation of a combination contraceptive / antiretroviral IVR
- Moving rectal microbicides towards Phase 3
  - Initiate a global Phase 2A study

# Challenges for the MTN

- The outcome of the ASPIRE study will determine the future direction of the MTN portfolio
- We all need to be ambassadors for topical microbicides!
  - Safety and acceptability
  - Access and affordability
  - Scalability
- The WHO guidelines for PrEP will increase the operational complexity of Phase 2B/3 effectiveness trials



# The Journey Continues





# Acknowledgements

- Our wonderful participants
- Our incredible site staff
- Our generous funders
  - The Microbicide Trials Network is funded by the National Institute of Allergy and Infectious Diseases (UM1AI068633, UM1AI068615, UM1AI106707), with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health