

MTN Regional Meeting Welcome to Cape Town



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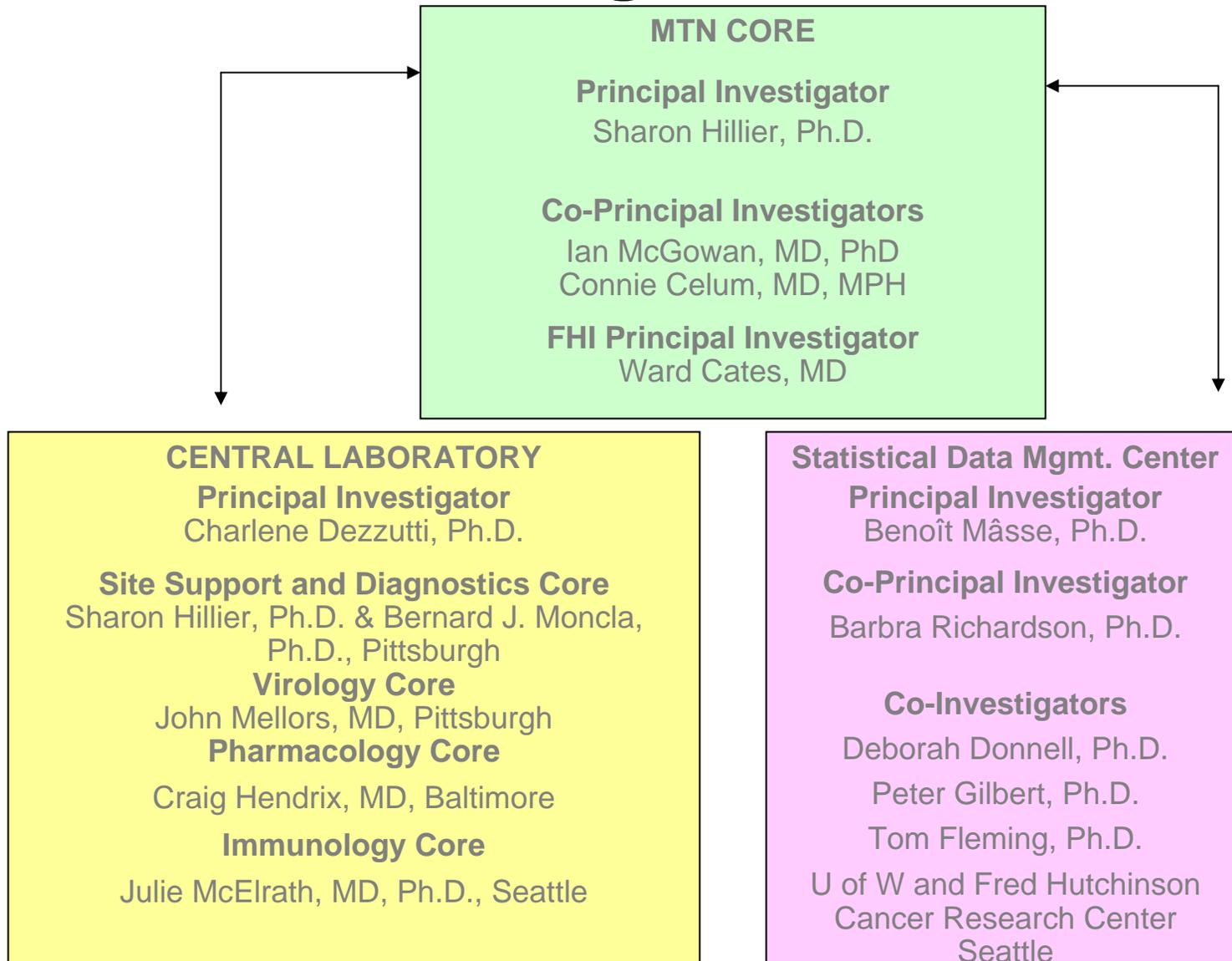
Origins of MTN

- First microbicide trials conducted in HIVNET 1995-2000
- Microbicide research agenda expanded in HPTN 2000-present
- MTN became independent of HPTN because of growing research agenda in a high priority area
- HPTN Microbicide Working Group researchers retained in MTN
- MTN grant submitted May 2005, awarded June 2006

What is the MTN and What is its Mission?

- **The Microbicide Trials Network (MTN), based at the Magee-Womens Research Institute of the University of Pittsburgh, is a worldwide collaborative clinical trials network that evaluates the safety and efficacy of microbicides designed to prevent HIV transmission.**
- **The mission of the MTN is to reduce the sexual transmission of HIV through the evaluation of products applied topically to mucosal surfaces or administered orally**

How is the MTN Leadership Organized?



MTN Executive Committee

Sharon Hillier, Pittsburgh CORE, Chair EC

Ian McGowan, UCLA

Connie Celum, Univ WA

Ward Cates, FHI

Ben Masse, SCHARP, Data Center PI

Charlene Dezzuttii, Pittsburgh, Network Lab PI

Pamina Gorbach, UCLA, Behavioral Research Committee
representative

Jeanne Marrazzo, Univ WA, Biomedical Science
Committee representative

Salim Abdool-Karim, S Africa, Clinical Care

MTN Executive Committee

- Sharon Riddler (USA), Domestic CTU representative
- Clemensia Nakabiito (Uganda), International CTU representative
- Gita Ramjee (S Africa), International CTU representative
- **Morenike Ukpong (Nigeria)- Community Working Group Chair**
- Roberta Black, NIH DAIDS representative
- Kevin Ryan, NIH NICHD representative
- Andrew Forsyth, NIH NIMH representative

MTN Executive Committee

EXECUTIVE COMMITTEE IS DIVERSE

- Four US based representatives from CORE (Hillier, McGowan, Cates, Celum), 2 from science working groups, and 1 each from lab and data center, 3 from NIH, 1 domestic site
- Four (25%) of 16 Executive Committee members are international investigators (Abdool-Karim, Nakabiito, Ramjee, **Ukpong**)
- 9 of 16 EC members are women

MTN: Focused Microbicide R&D Strategy

- **Provide what our funders need**
 - More time and cost efficient clinical trials which will produce clinical trial data of regulatory quality, incorporating best science
- **Address investigator objectives**
 - To delivery high quality trials in HIV prevention, to integrate cutting edge science, to garner the financial resources to make it happen
- **Consider site and community perspectives**
 - Clear vision, to be included in science development at earliest stages, maintain pipeline of protocols to keep sites engaged

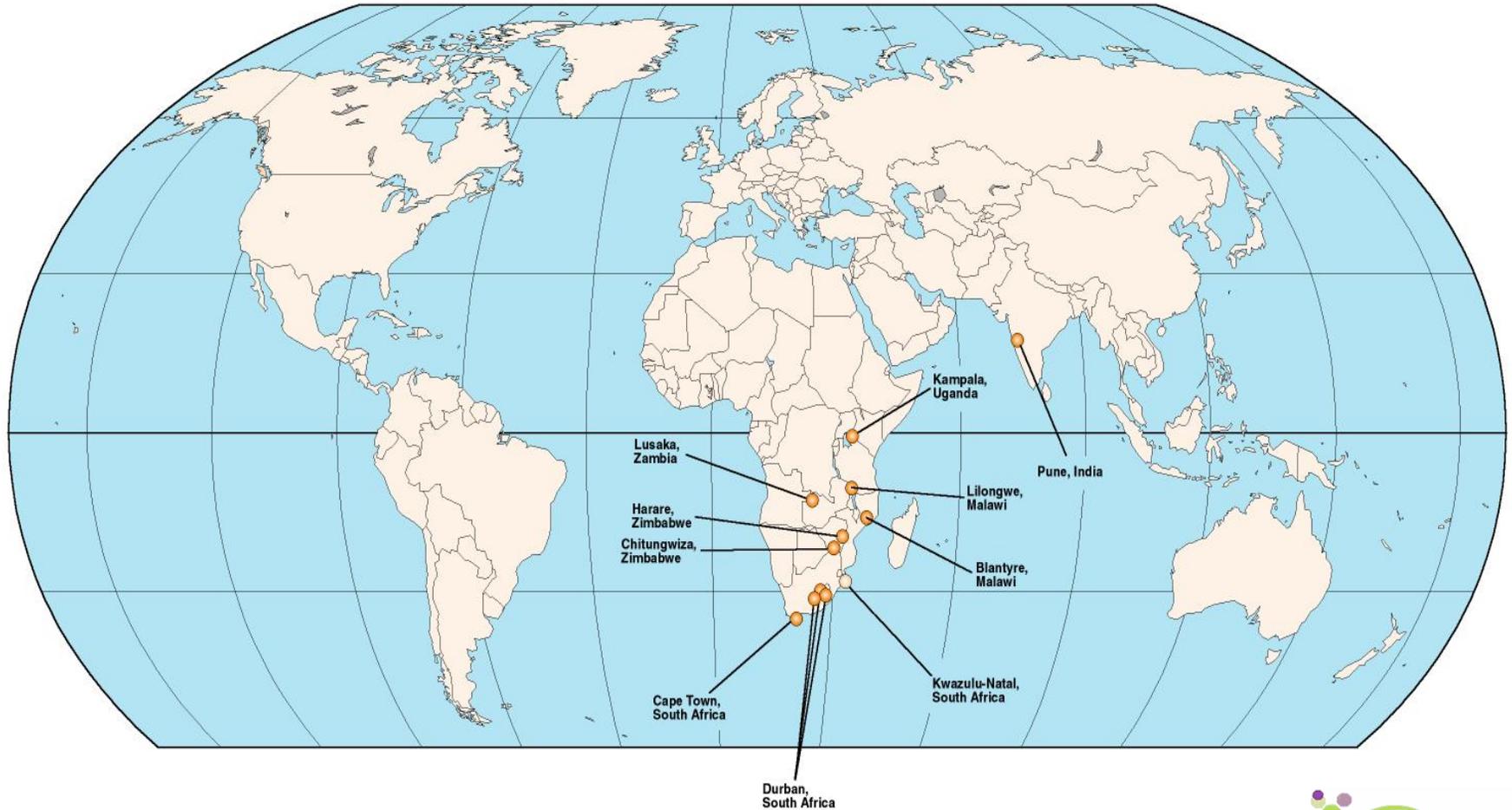
What Questions Does MTN Hope to Answer?

Over 7 years of funding (2006-2013) we will answer these questions:

- Can a chemoprophylactic agent applied topically or orally at least partially prevent HIV infection in women?**
- How can we best measure safety of topically applied microbicides?**
- How acceptable are these products to women and their partners, and can we best measure adherence and its impact on effectiveness?**
- How can we move into other high risk populations: Pregnant women; adolescents**
- Which strategy makes more sense for ART prophylaxis in women: oral or topical?**

MTN – Clinical Research Sites for Initial Trials – Outside U.S.

Full CRS Other CRS
● MTN ●



What Will Be the MTN's Focus and Plan of Action?

- **Focus**

- Drug development paradigm
- Regional clinical trials support
- Optimized safety review
- Enhanced laboratory collaboration
- Integrated behavioral science
- Strong community involvement

- **Plan of Action**

- Execution of 15 clinical trials of microbicides over 7 years
- Focused, timeline-driven research agenda

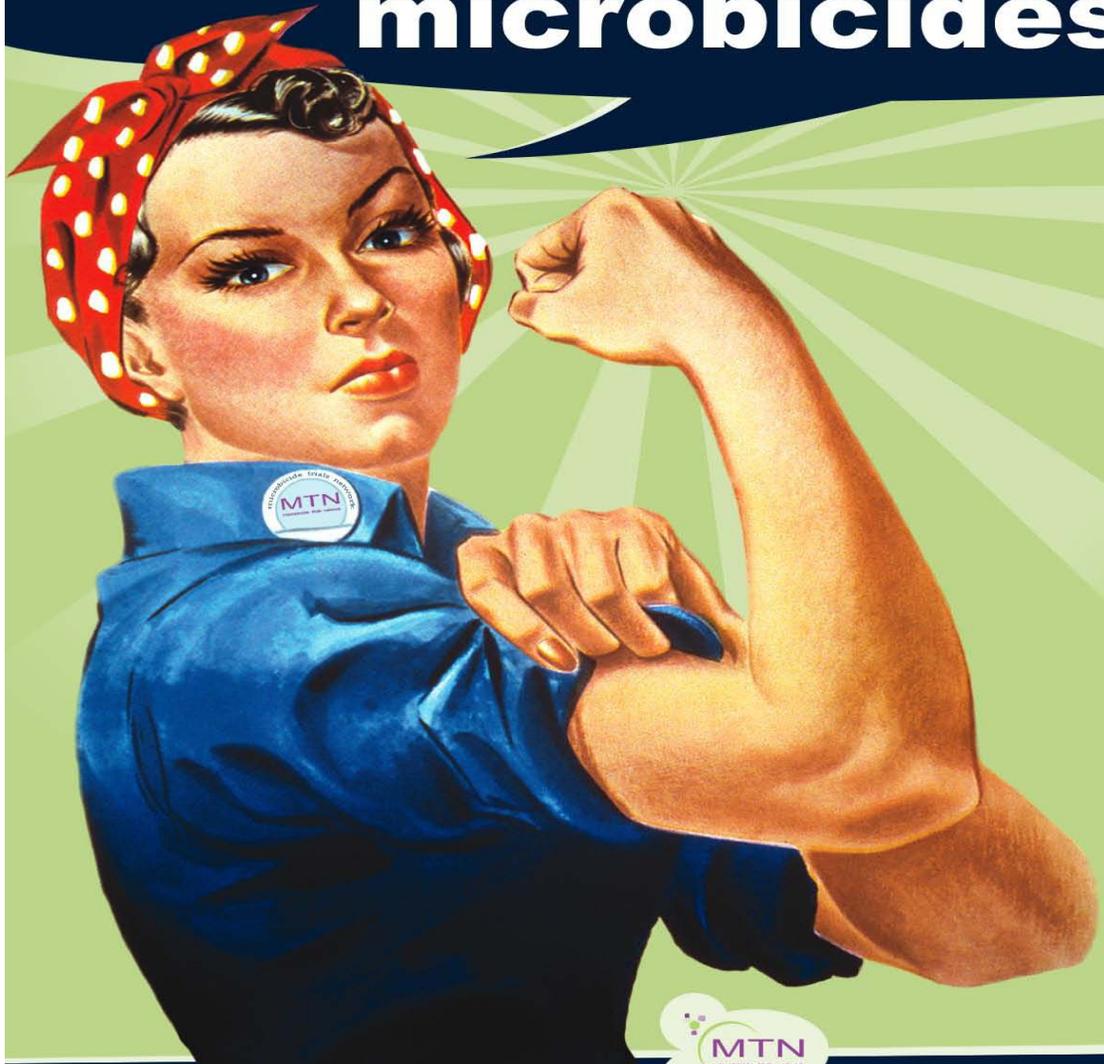
MTN Regional Meeting Objectives

- To build the MTN team- vision and objectives
- To build communications strategies for whatever happens next- good or bad
- To share lessons and strategies across network components
- To solicit site and community input on MTN-001 and 003
- To conduct an operational walkthrough of 015
- To choose a name for MTN-003!

The Next Big MTN Study (MTN-003) Naming Contest

- We are challenging you to help find a name for the next big MTN study. We want to find a name to describe this study and provide a way for everyone around the world to recognize the study.
 - Example: Top Ten Study = Topical Tenofovir Study
- Please enter your best idea for the study name and hand-in your entry to Sharon Hillier or other MTN CORE staff before Wednesday evening. A panel of judges will select the best name.
- The team submitting the winning name will receive a prize from the MTN
- **WE NEED YOUR CREATIVITY!!!**

the power of **HIV** prevention through microbicides



microbicide trials network



www.mtnstopshiv.org

MTN: Who they think we are

- A new research network just getting started
- A group of investigators chasing an impossible dream- studies too hard and too big to be done
- A group still thinking about products like N-9 rather than cutting edge science

MTN: Who We Are

- We care about prevention of HIV
- We know that we need several approaches to prevention are needed to change the face of this epidemic
- We are not afraid of hard work
- We are committed to excellence
- We do the impossible every day so that we can change the face of this epidemic