

Welcome to the MTN: State of the Network

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Professor

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and Reproductive Sciences

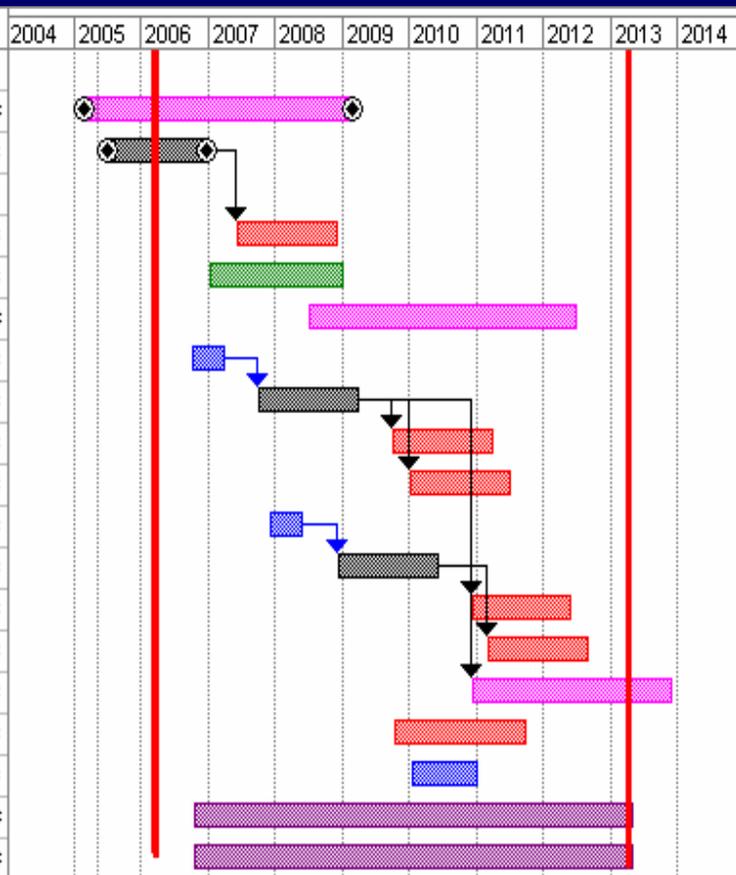
University of Pittsburgh

Magee-Womens Hospital

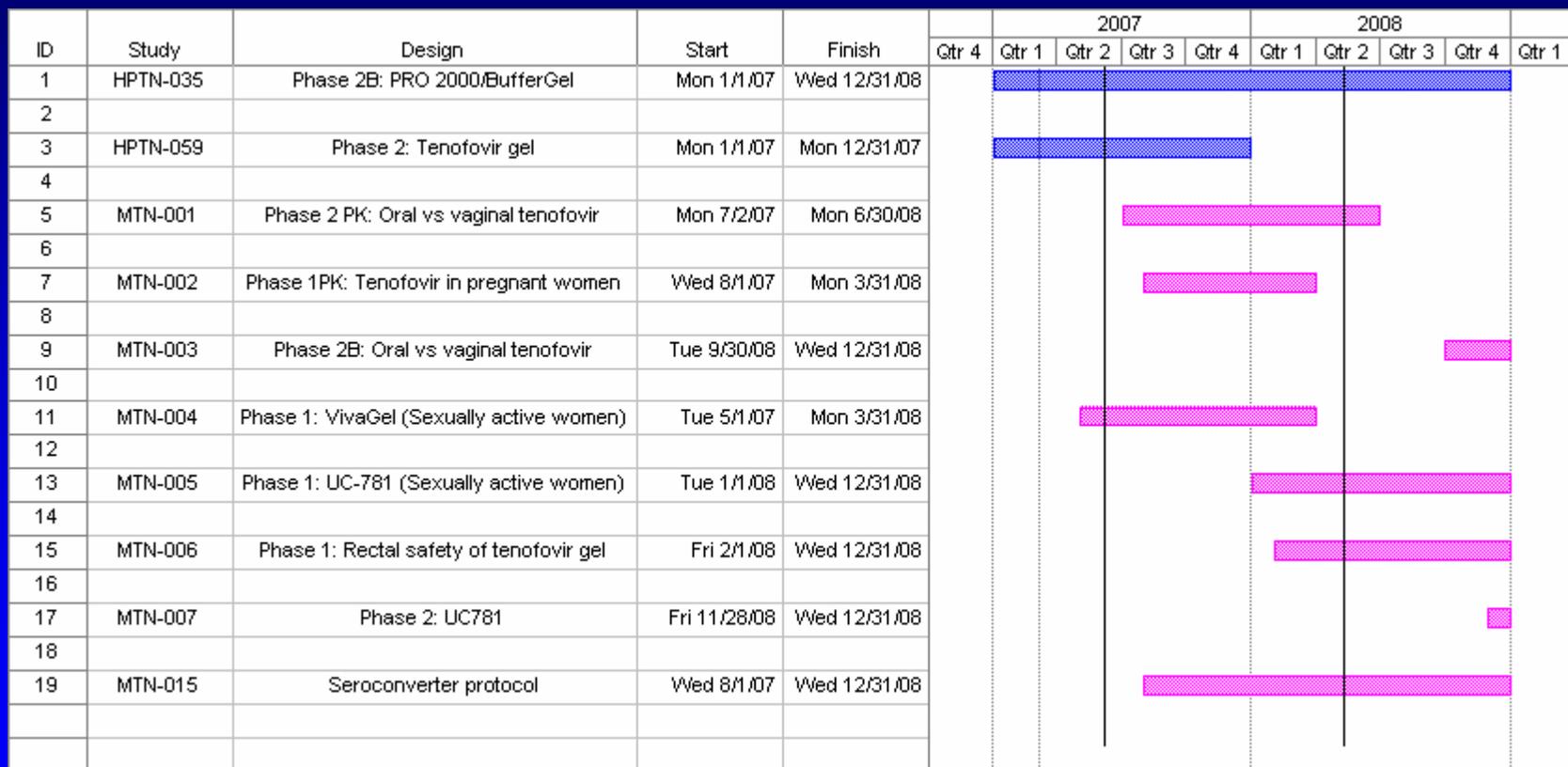


Proposed Gantt Chart of Clinical Trial Activity in the MTN May 2005

ID	Task Name	Product (s)	Population	Phase	N	Duration	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
2																	
3	HPTN-035	BG, Pro2000	HIV Neg	2B	3220	1040 days											
4	HPTN-059	PMPA	HIV Neg	2	200	390 days											
5																	
6	MTN-001	PMPA	HIV Pos	1	45	390 days											
7	MTN-002	N/A	HIV Neg	Prep	1500	520 days											
8	MTN-003	TDF, PMPA	HIV Neg	2B	3000	1040 days											
9	MTN-004	CCR5	HIV Neg	1	30	130 days											
10	MTN-005	FI, CCR5	HIV Neg	2	300	390 days											
11	MTN-006	FI	HIV Pos	1	45	390 days											
12	MTN-007	CCR5	HIV Pos	1	45	390 days											
13	MTN-008	RTI ring	HIV Neg	1	30	130 days											
14	MTN-009	RTI, RTI ring	HIV Neg	2	300	390 days											
15	MTN-010	RTI	HIV Pos	1	45	390 days											
16	MTN-011	RTI ring	HIV Pos	1	45	390 days											
17	MTN-012	RTI, FI, CCR5	HIV Neg	2B	4900	780 days											
18	MTN-013	RTI	HIV Neg + HIV Pos	1	60	520 days											
19	MTN-014	Rectal TBD	HIV Neg	1	30	260 days											
20	MTN-015	N/A	HIV Pos	Seroconverter	300	1712 days											
21	MTN-016	N/A	HIV Pos	Registry	225	1712 days											



Gantt Chart of Current and Proposed Clinical Trial Activity in the MTN as of March 2007



Objectives for MTN During Year 1

- Continue enrollment and follow-up of women on HPTN 035
- Initiate and complete enrollment of women on HPTN 059
- Develop a seroconverter protocol
- Establish a collaboration with the Adolescent Trials Network
- Collaborate with NIH on the development of new toxicity tables for use in microbicide studies
- Develop infrastructure and manual of procedures for MTN
- Develop a website

MTN: The View at 9 Months

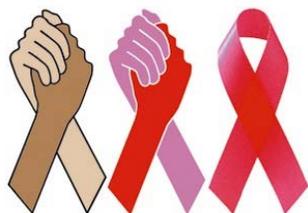
Since July 1, 2006 the MTN Has:

- Screened 2,484 women for HPTN 035, enrolled 1,303 women and completed 11,077 follow-up study visits. Our monthly accrual has been 145 women.
- Screened 275 women for HPTN 059, enrolled 180 women and completed 383 follow-up study visits. Our monthly accrual has been 23 women.
- For HPTN 035 & 059 combined; screened 2,759 women, enrolled 1,483 women and completed 11,460 follow-up study visits. Our monthly accrual has been 165 women.
- 92,124 forms have been received at SCHARP during this time period

MTN: The View At 9 Months



- Established formal collaboration with ATN
- Developed path for collaboration on MTN 004 safety study of VivaGel
- Sites in Tampa, FL and San Juan PR



ADOLESCENT **T**RIALS **N**ETWORK
for HIV/AIDS Interventions
Prevention and Care for Today's Youth



University of South Florida

Diane Straub, MD, MPH



MTN-004



University of Puerto Rico

Irma Febo, MD



MTN-004

MTN: The View At 9 Months

- Launched expedited protocol development paradigm as described in application
- Draft of protocol developed with small internal team and distribution to DAIDS, NICHD, NIMH for comment
- Face-to-face meeting to create nearly final version of protocol
- **MTN 004 developed from concept to PSRC approved protocol within 6 months of MTN funding!**
- Developed seroconverter protocol (MTN-015) which will be reviewed at PSRC April 3, 2007

MTN: The View at 9 Months

- MTN Leadership collaborated with DAIDS and DMID program officers to develop new DAIDS toxicity tables (November 2-3, 2006) for use by researchers in the microbicide field
- These forms have been submitted for final approval and have been provided to other microbicide researchers in the Quick Working Group

MTN: The View At 9 Months

- Developed basic infrastructure and web design – July and August 2006
- Mtnstopshiv.org goes live – September 2006
- IT and administrative group attended the DAIDS ES meeting – October 2006
- Meeting minutes and study documents – December 2006
- January 2007:
 - » Network directory available
 - » E-mail alias lists for all groups available through website
 - » Event calendar functions



MTN

microbicide trials network



MTN

microbicide trials network

SEARCH

home about contact links

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Navigation

- home
- contact
- documents
- network directory
- search
- studies



previous

next

“ If you advise your husband to use a condom, he may beat you and send you away. Where do you go then? ”

Rural woman
Uganda

Welcome to The Microbicide Trials Network >>



Updated Wed, 2006-11-22 11:28
Published Mon, 2006-11-13

INTRODUCTION

The Microbicide Trials Network (MTN), part of the [Magee-Womens Research Institute and Foundation](#) with affiliations to [Magee-Womens Hospital](#) of UPMC and the [University of Pittsburgh](#), will be 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 microbicide products. The MTN will conduct scientifically rigorous and ethically sound clinical trials that will support licensure of topical microbicide products. The MTN also to



Representation of HIV-1 structure

Latest postings

IATA Shipping Regulations Effective January 1, 2007
Wed, 2006-12-20 10:46

MTN Leadership - Conference Call Minutes Oct 06
Mon, 2006-12-18 15:46

MTN Leadership - Conference Call Minutes Aug 06
Mon, 2006-12-18 15:46

Microbicide news

Liquid Condoms: What's in a Name? (Time Magazine)
Tue, 2007-01-02 14:08



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- home
- contact
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next

“ Currently, women have no way to protect themselves except condoms, and women do not control condom use... ”

Dr. Sharon L. Hillier, Ph.D.
MTN Director

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Microbicide news

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Tue, 2007-01-02 14:09

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Representation of HIV-1 structure

Established by the [Division of AIDS](#) of the National Institute of Allergy and Infectious Diseases, in partnership with other collaborating institutes at the National Institute of Health (NIH), the MTN carries out its mission through a strong network of expert scientists and investigators from domestic and international sites.

WHAT IS A MICROBICIDE?

Microbicide refers to a range of different products that share one common characteristic - the capacity to prevent the sexual transmission of HIV and other sexually transmitted diseases (STDs) when applied topically. A microbicide could be produced in many forms, including gels, creams, suppositories, films, or as a sponge or ring that releases the active ingredient over time.

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Sharon Hillier

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Microbicide news

MAILING ADDRESS

Magee-Womens Hospital of UPMC
Department of OB/GYN and
Reproductive Sciences
300 Halket Street
Pittsburgh, PA 15213
United States

SHIPPING ADDRESS

Magee-Womens Hospital of UPMC
Department of OB/GYN and
Reproductive Sciences
300 Halket Street
Pittsburgh, PA 15213
United States

MY INVOLVEMENT WITH THE MTN

HPTN 035	Co-Chair
HPTN 059	Protocol Chair
CORE	Principal Investigator
MTN-004	Principal Investigator

MY EMAIL GROUPS

Who Are Our Domestic Sites?

Bronx-Lebanon Hospital, Bronx, NY

Jessica Justman, MD & Wafaa El-Sadr, MD, MPH



Bronx Lebanon
Hospital Center

HPTN 059

University of Alabama at Birmingham

Craig J. Hoesley, MD



HPTN 059



University of Pennsylvania and CHOP

Lisa Maslankowski, MD & Johnnita Prince



HPTN 035



John W. Mellors, MD & Sharon A. Riddler, MD University of Pittsburgh



MTN-001



Case Western Reserve University

Michael Lederman, MD



MTN-001

Who Are Our International Sites?

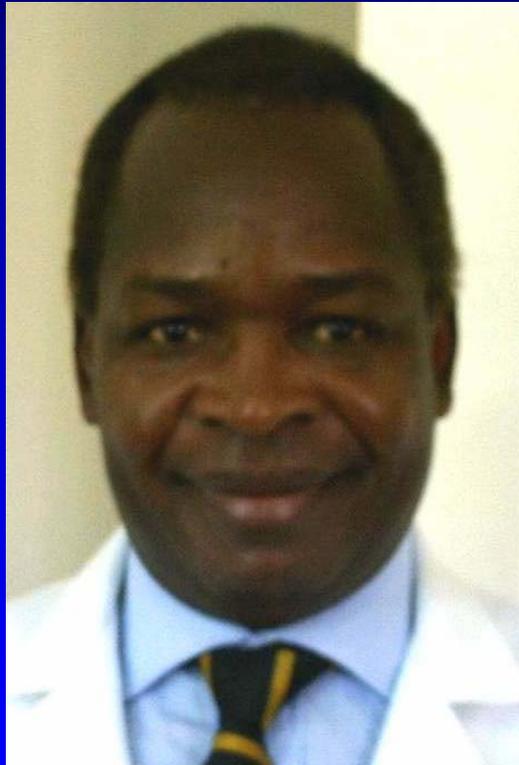
National AIDS Research Institute, Pune India

Smith Joshi, MBBS & Dr. Mehendale



HPTN 059

Mike Chirenje, MD, MCROG & Tsitsi Magure UZ-UCSF Collaborative Research Programme- Zimbabwe



HPTN 035



Lilongwe Central Hospital, Malawi

Francis Martinson, MD, Ph.D. & Bonus Makanani, MBS



HPTN 035

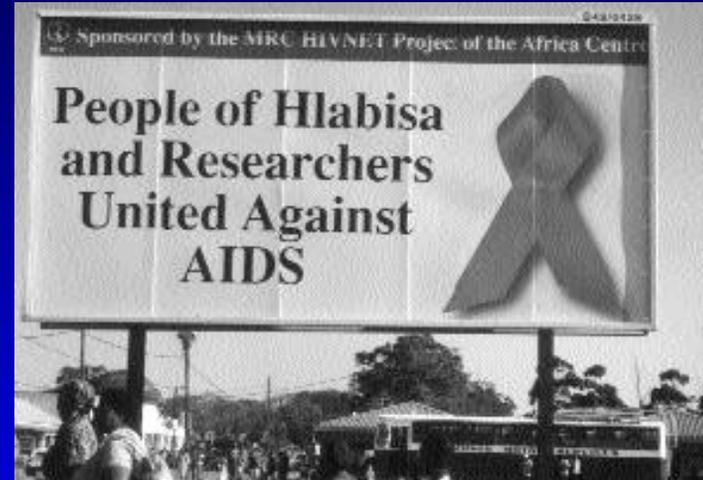
Queen Elizabeth Hospital Blantyre Malawi Taha Taha, MD & Newton Kumwenda, Ph.D.



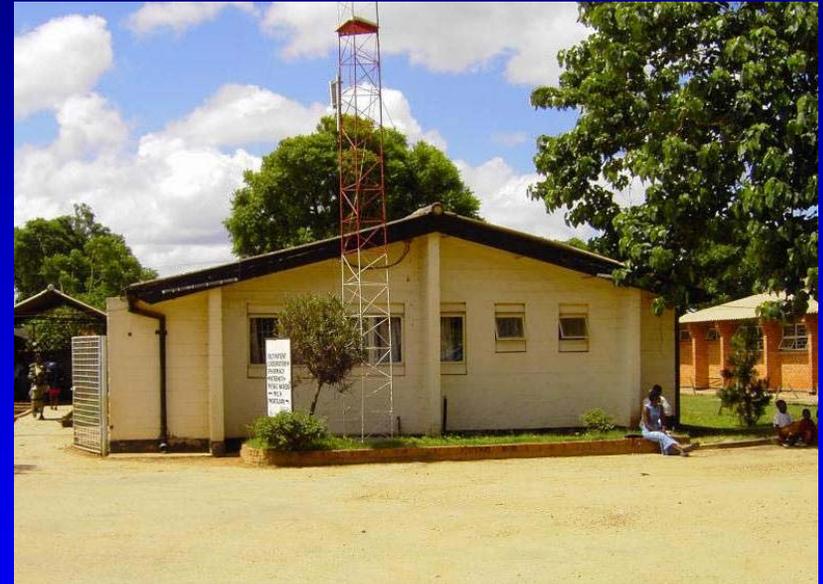
HPTN 035

Hlabisa & Chatsworth, South Africa

Gita Ramjee, Ph.D. & Roshini Govinden, Ph.D.



Lusaka Zambia



HPTN 035

Kampala Uganda

Laura A. Guay, MD, Francis Mmiro, MBBS, FICS, FRCOG & Clemensia Nakabiito, MBChB, M.Med



MTN-001

Umkomaas & Botha's Hill, South Africa

Gita Ramjee, Ph.D.



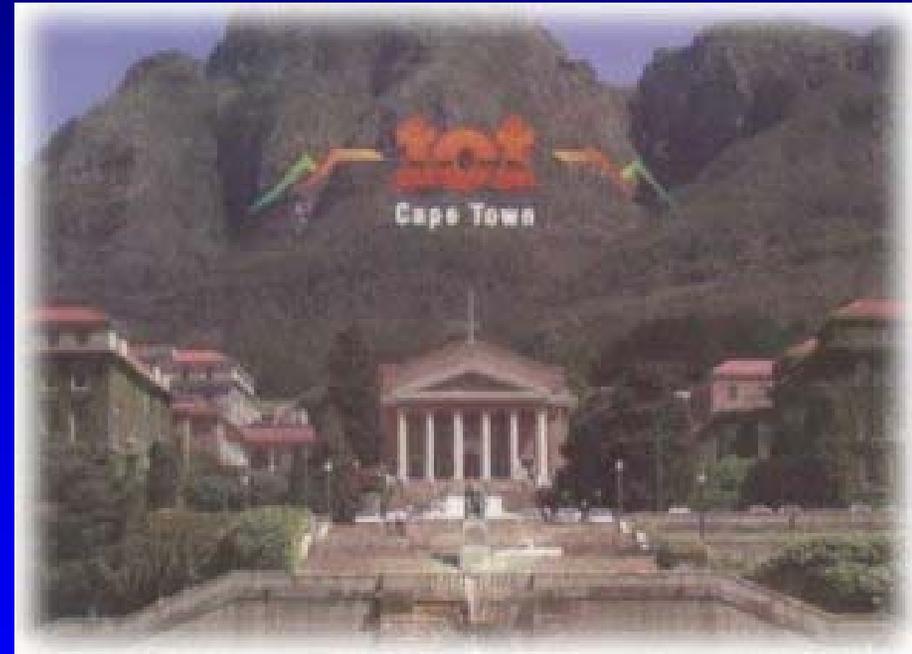
Umkomaas



Botha's Hill

Cape Town, South Africa

David Coetzee, MBBS, MS, DTM&H



MTN-001



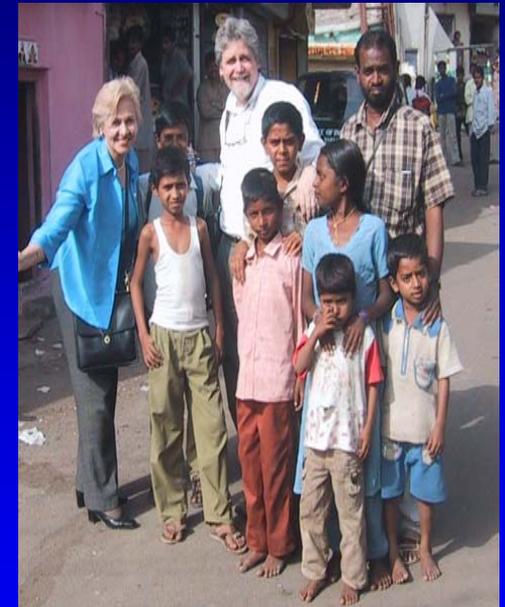
NIAID Partners



Dr. Sandra Lehrman

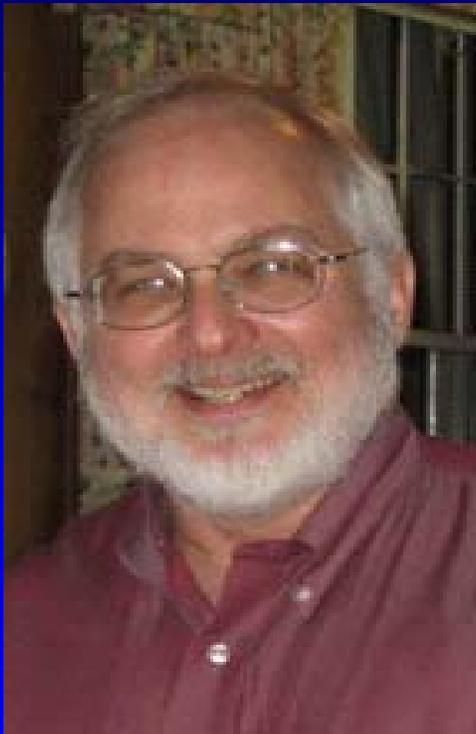


Dr. Roberta Black Dr. Jeanna Piper



Lydia E. Soto-Torres, MD, MPH

NICHD



Kevin W. Ryan, Ph.D.



D. Heather Watts, MD



Bill G. Kapogiannis, MD

NIMH

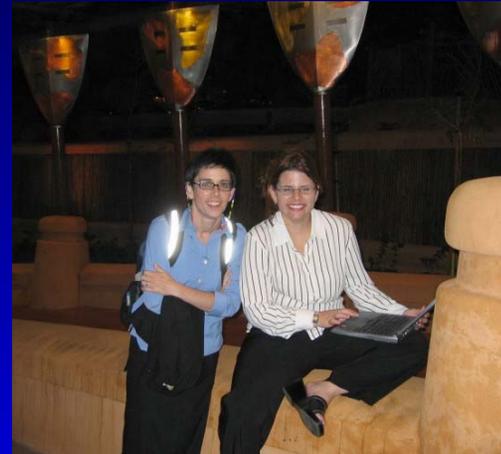
Andrew D. Forsyth, Ph.D.



Family Health International



Ward Cates, MD, MPH



Anne Coletti & Kailazarid Gomez



Sheila Clapp



**Statistical Center for HIV/AIDS Research &
Prevention (SCHARP)
Fred Hutchinson Cancer Research Center
Benoît R. Mâsse, Ph.D.**



MTN CORE and Network Laboratory Pittsburgh, PA



MTN Leadership Group Meeting September 12, 2006



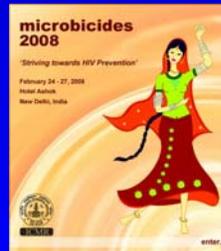
Which Meeting Should You Go To Tomorrow?

- HPTN 035 (8:00 AM-12:00 PM, Hoover)
- MTN-004 (8:00 AM-10:00 AM, Harding)
- HPTN 059 (10:00 AM-12:00 PM, Harding)
- MTN-015 (1:00 PM-2:00 PM, Hoover)
- MTN-001 (1:00 PM-2:00 PM, Harding)
- MTN-035B (2:00 PM-3:00 PM, Hoover)
- MTN-003 (3:00 PM-5:00 PM, Hoover)

All sites should make a time to talk to the webmaster (Tuesday and Wednesday, 8:00 AM-12:00 PM, McKinley) and with Melissa DeGore about budgets (Wednesday, 1:00-4:00 PM, Wilson C)

MTN: The View at 9 Months

- We met our major objectives for: HTPN 035, 059, development of a seroconverter protocol and formed a collaboration with ATN
- We have developed a vigorous scientific agenda to move forward with new studies for 2007-2008
- Regional meeting will be held May 22-24, 2007 in Cape Town South Africa
- Plan to attend the M2008 meeting in New Delhi India February 24-27, 2008



- Next annual meeting will be in May 2008, WA, DC