Welcome to the MTN: State of the Network

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University of Pittsburgh
Magee-Womens Hospital
# Proposed Gantt Chart of Clinical Trial Activity in the MTN May 2005

<table>
<thead>
<tr>
<th>ID</th>
<th>Task Name</th>
<th>Product(s)</th>
<th>Population</th>
<th>Phase</th>
<th>N</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>HPTN-035</td>
<td>EFV, Pro2000</td>
<td>HIV Neg</td>
<td>2B</td>
<td>3220</td>
<td>1040 days</td>
</tr>
<tr>
<td>4</td>
<td>HPTN-059</td>
<td>PMPA</td>
<td>HIV Neg</td>
<td>2</td>
<td>200</td>
<td>390 days</td>
</tr>
<tr>
<td>5</td>
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<td></td>
</tr>
<tr>
<td>6</td>
<td>MTN-061</td>
<td>PMPA</td>
<td>HIV Pos</td>
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<td>45</td>
<td>390 days</td>
</tr>
<tr>
<td>7</td>
<td>MTN-062</td>
<td>N/A</td>
<td>HIV Neg</td>
<td>Prep</td>
<td>1500</td>
<td>520 days</td>
</tr>
<tr>
<td>8</td>
<td>MTN-063</td>
<td>TDF, PMPA</td>
<td>HIV Neg</td>
<td>2B</td>
<td>3000</td>
<td>1040 days</td>
</tr>
<tr>
<td>9</td>
<td>MTN-064</td>
<td>CCR5</td>
<td>HIV Neg</td>
<td>1</td>
<td>30</td>
<td>130 days</td>
</tr>
<tr>
<td>10</td>
<td>MTN-065</td>
<td>FI, CCR5</td>
<td>HIV Pos</td>
<td>2</td>
<td>300</td>
<td>390 days</td>
</tr>
<tr>
<td>11</td>
<td>MTN-066</td>
<td>FI</td>
<td>HIV Pos</td>
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<td>45</td>
<td>390 days</td>
</tr>
<tr>
<td>12</td>
<td>MTN-067</td>
<td>CCR5</td>
<td>HIV Pos</td>
<td>1</td>
<td>45</td>
<td>390 days</td>
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<tr>
<td>13</td>
<td>MTN-068</td>
<td>RTI Ring</td>
<td>HIV Neg</td>
<td>1</td>
<td>30</td>
<td>130 days</td>
</tr>
<tr>
<td>14</td>
<td>MTN-069</td>
<td>RTI, RTI Ring</td>
<td>HIV Neg</td>
<td>2</td>
<td>300</td>
<td>390 days</td>
</tr>
<tr>
<td>15</td>
<td>MTN-070</td>
<td>RTI</td>
<td>HIV Pos</td>
<td>1</td>
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<td>390 days</td>
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<tr>
<td>16</td>
<td>MTN-071</td>
<td>RTI Ring</td>
<td>HIV Pos</td>
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<td>45</td>
<td>390 days</td>
</tr>
<tr>
<td>17</td>
<td>MTN-072</td>
<td>RTI, FI, CCR5</td>
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<td>2B</td>
<td>4500</td>
<td>780 days</td>
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<td>RTI</td>
<td>HIV Neg + HIV Pos</td>
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<td>Rectal TBD</td>
<td>HIV Neg</td>
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<td>MTN-075</td>
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<td>Seroconverter</td>
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<td>MTN-076</td>
<td>N/A</td>
<td>HIV Pos</td>
<td>Registry</td>
<td>225</td>
<td>1712 days</td>
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</table>
## Gantt Chart of Current and Proposed Clinical Trial Activity in the MTN as of March 2007

<table>
<thead>
<tr>
<th>ID</th>
<th>Study</th>
<th>Design</th>
<th>Start</th>
<th>Finish</th>
<th>2007</th>
<th>2008</th>
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<tbody>
<tr>
<td>1</td>
<td>HFTN-035</td>
<td>Phase 2B: FRO 2000/BufferGel</td>
<td>Mon 1/1/07</td>
<td>Wed 12/31/08</td>
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<td>3</td>
<td>HFTN-058</td>
<td>Phase 2: Tenofovir gel</td>
<td>Mon 1/1/07</td>
<td>Mon 12/31/07</td>
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<td>4</td>
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<tr>
<td>5</td>
<td>MTN-001</td>
<td>Phase 2 PK: Oral vs vaginal tenofovir</td>
<td>Mon 7/2/07</td>
<td>Mon 5/30/08</td>
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<td>Phase 1PK: Tenofovir in pregnant women</td>
<td>Wed 8/1/07</td>
<td>Mon 3/31/08</td>
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<tr>
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<td>MTN-003</td>
<td>Phase 2B: Oral vs vaginal tenofovir</td>
<td>Tue 9/30/08</td>
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<td>MTN-004</td>
<td>Phase 1: VivaGel (Sexually active women)</td>
<td>Tue 5/1/07</td>
<td>Mon 3/31/08</td>
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<tr>
<td>13</td>
<td>MTN-005</td>
<td>Phase 1: UC-781 (Sexually active women)</td>
<td>Tue 1/1/08</td>
<td>Wed 12/31/08</td>
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<td>15</td>
<td>MTN-006</td>
<td>Phase 1: Rectal safety of tenofovir gel</td>
<td>Fri 2/1/08</td>
<td>Wed 12/31/08</td>
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<td>MTN-007</td>
<td>Phase 2: UC781</td>
<td>Fri 11/28/08</td>
<td>Wed 12/31/08</td>
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<td>19</td>
<td>MTN-015</td>
<td>Seroconverter protocol</td>
<td>Wed 8/1/07</td>
<td>Wed 12/31/08</td>
<td></td>
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</tbody>
</table>
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
University of South Florida
Diane Straub, MD, MPH

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 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
Welcome to The Microbicide Trials Network

INTRODUCTION

The Microbicide Trials Network (MTN), part of the "Hepatitis Treatment Board" and the "Hepatitis Prevention Board," 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 novel microbicide products. The MTN aims to...

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

Dr. Sharon L. Hiller, Ph.D.
MTN Director
Welcome to The Microbicide Trials Network

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 plans to develop and/or execute 15 separate clinical trials of microbicides between 2006 and 2013.

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.
Sharon Hillier

Quick Links
addresses | mtn | email lists | about me

Sharon Hillier Ph.D.

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- fax: 412-641-1133

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United States

Shipping Address
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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

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
Who Are Our International Sites?
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
Umkomaas & Botha’s Hill, South Africa
Gita Ramjee, Ph.D.
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
Family Health International

Ward Cates, MD, MPH

Sheila Clapp

Anne Coletti & Kailazarid Gomez
MTN CORE and Network Laboratory
Pittsburgh, PA
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