

# the power of **HIV** prevention through microbicides



May 21 - 24  
**2007**

Microbicide Trials Network  
Regional Meeting  
Cape Town, South Africa





**MTN Regional Meeting Agenda**  
**International Convention Centre**  
**Cape Town, South Africa**  
**May 21-24, 2007**

Monday, May 21, 2007	
8:00 AM to 8:30 AM	Welcome and Introductions
8:30 AM to 9:30 AM	HPTN 035 Milestones and Accomplishments
9:30 AM to 11:30 AM	Overview of Study Quality and Safety Monitoring Processes for HPTN 035
11:30 AM to 1:00 PM	Adherence to Product Use
1:00 to 2:00 PM	<b>LUNCH</b>
2:00 PM to 6:00 PM	Breakout Sessions: Media Training for Primary Spokespersons from Each Site – Manuscript Development Training for All Interested Team Members
6:00 PM	Adjourn

**Tuesday, May 22, 2007**

7:00 AM to 8:00 AM	Registration and Continental Breakfast
8:00 AM to 8:15 AM	Welcome and Introduction to the MTN Structure <b>Sharon L. Hillier, Ph.D.</b>
8:15 AM to 8:30 AM	Welcome from the NIH: Introduction of Microbicides <b>Roberta J. Black, Ph.D., Mary Fanning, MD, Ph.D., Andrew D. Forsyth, Ph.D.</b>
8:30 AM to 9:00 AM	State of the Art in Microbicide Research - <b>Sharon L. Hillier, Ph.D.</b>
9:00 AM to 9:15 AM	HPTN 035 - <b>Professor Salim S. Abdool Karim</b>
9:15 AM to 9:45 AM	MTN-035B: An Alternative Approach to Measuring Behaviors <b>Pamina M. Gorbach, MHS, Dr.PH</b>
9:45 AM to 10:00 AM	MTN-015 - <b>Sharon A. Riddler, MD, MPH</b>
10:00 AM to 10:30 AM	<b>BREAK</b>
10:30 AM to 11:30 AM	Moving Forward with ART Based Microbicides <b>Sharon L. Hillier, Ph.D.</b>
11:30 AM to 12:00 PM	ART Resistance and Microbicides <b>Ian McGowan, MD, Ph.D.</b>
12:00 PM to 12:30 PM	Discussion of ART Portfolio <b>Connie L. Celum, MD, MPH, Patrick Ndase, MBChB, MPH</b>
12 :30 PM to 1 :00 PM	Other Microbicides : MTN-004 - <b>Ian McGowan, MD, Ph.D.</b>
1 :00 PM to 2 :00 PM	<b>LUNCH</b>
2 :00 PM to 2 :30 PM	Communications : Why a Communication Plan is Essential <b>Global Health Strategies</b>
2:30 PM to 2:45 PM	Brief Case Studies <b>Dr. David Coetzee, Professor Gita Ramjee, Morenike Ukpong</b>
2:45 PM to 3:00 PM	Panel Discussion
3:00 PM to 3:30 PM	<b>BREAK</b>
3:30 PM to 3:45 PM	Site Presentations - Blantyre
3:45 PM to 4:00 PM	Cape Town
4:00 PM to 4:30 PM	Durban (All Sites)
4:30 PM to 4:45 PM	Harare
4:45 PM to 5:00 PM	Kampala
5:00 PM to 5:15 PM	Lilongwe
5:15 PM to 5:30 PM	Lusaka
5:30 PM to 6:00 PM	Wrap-up and Review of Meeting Objectives for Day 2
6:00 PM	Dinner on your own



Wednesday, May 23, 2007 – Laboratory Breakout  
Facilitators: Charlene S. Dezzutti, Ph.D. & Lorna K. Rabe

8:00 AM to 8:15 AM	Introduction and Welcome
8:15 AM to 8:30 AM	Probetec Issues <b>Lorna K. Rabe</b>
8:30 AM to 9:00 AM	MTN MOP Introduction <b>Pam Kunjara</b>
9:00 AM to 9:30 AM	Coagulation <b>Estelle Piwovar-Manning</b>
9:30 AM to 10:15 AM	HIV Rapid Tests & HIV WB Issues <b>Estelle Piwovar-Manning</b>
10:15 AM to 10:45 AM	<b>BREAK</b>
10:45 AM to 12:00 PM	Lab Presentations (Durban-Chain of Custody, Blantyre-Hematology, Lilongwe-Coagulation, Lusaka-Probetec, Harare-HIV Rapid & Western Blot)
12:00 PM to 1:00 PM	Small Group Discussion-Lab Problem Resolution
1:00 PM to 2:00 PM	<b>LUNCH</b>
2:00 PM to 2:45 PM	Small Group Discussion-Lab Problem Resolution (continued)
2:45 PM to 3:15 PM	<b>BREAK</b>
3:15 PM to 4:15 PM	HPTN/MTN Lab Manual Session <b>Yaw Agyei, Lebah Lugalila</b>
4:15 PM to 5:00 PM	Use of HPTN/MTN Lab Tools Excel Spreadsheet <b>Ted Livant</b>



**Wednesday, May 23, 2007 – Pharmacy Breakout**  
**Facilitators: Cindy Jacobson, Pharm D & Ana Martinez**

8:00 to 8:30 AM	Introduction and Welcome <b>Cindy Jacobson, Ana Martinez</b>
8:30 AM to 9:30 AM	Upcoming Changes in the DAIDS Pharmacy Guidelines & Instructions for Clinical Trials Networks <b>Scharla Estep</b>
9:30 AM to 10:15 AM	Pharmacy Issues Associated with HPTN 035 <b>Scharla Estep</b>
10:15 AM to 10:45 AM	<b>BREAK</b>
10:45 AM to 1:00 PM	MTN-003 Rationale & Proposed Design/Suggestions for Dispensing Study Product & Packaging <b>Cindy Jacobson</b>
1:00 PM to 2:00 PM	<b>LUNCH</b>
2:00 PM to 2:45 PM	MTN-003: Suggestions for Dispensing Study Product & Packaging (continued)
2:45 PM to 3:15 PM	<b>BREAK</b>
3:15 PM to 4:00 PM	Randomization
4:00 PM to 5:00 PM	Identification of Action Items and Next Steps

Wednesday, May 23, 2007 – Community Breakout Facilitators: Morenike Ukpong & Rhonda White	
8:00 AM to 9:00 AM	Welcome, MTN & Community Program Overviews ( <b>Hillier, Ukpong</b> )
9:00 AM to 9:30 AM	What Does Safety Mean in the MTN? ( <b>Harwood, Connolly</b> )
9:30 AM to 10:15 AM	Community Participation in Concept & Protocol Development ( <b>Noguchi, Ukpong, White</b> )
10:15 AM to 10:45 AM	<b>BREAK</b>
10:45 AM to 12:00 PM	MTN-003: What is it & What are our Questions/Concerns/Suggestions for Improvement? How will our Community React to this Study? ( <b>Hillier, Ukpong, White</b> )
12:00 PM to 1:00 PM	Media Training for Community Staff & Representatives ( <b>Global Health Strategies, Rossi</b> )
1:00 PM to 2:00 PM	<b>LUNCH</b>
2:00 PM to 2:45 PM	Media Training (continued) ( <b>Global Health Strategies, Rossi</b> )
2:45 PM to 3:15 PM	<b>BREAK</b>
3:15 PM to 4:45 PM	Medical Training (continued) ( <b>Global Health Strategies, Rossi</b> )
4:45 PM to 5:00 PM	Wrap-up, Identification of Action Items ( <b>Ukpong, White</b> )



Wednesday, May 23, 2007 - Clinicians Breakout  
Facilitator: Patrick Ndase

8:00 AM to 10:15 AM	Clinicians' Role in Participant Recruitment, Retention, & Product Adherence
10:15 AM to 10:45 AM	<b>BREAK</b>
10:45 AM to 12:00 PM	Role of PSRT in Safety Monitoring of MTN Studies ( <b>Connolly, Harwood</b> )
12:00 PM to 1:00 PM	<b>LUNCH</b>
1:00 PM to 2:45 PM	Adverse Event Reporting Overview & Scenario Discussions ( <b>Connolly, Harwood</b> )
2:45 PM to 3:15 PM	<b>BREAK</b>
3:15 PM to 4:30 PM	Preparation for MTN-015: HIV/AIDS Natural History & Concurrent WHO Treatment Guidelines ( <b>Riddler, International Investigator TBN</b> )
4:30 PM to 5:00 PM	Wrap-up and Identification of Next Steps





Wednesday, May 23, 2007 – Site Investigators Breakout  
Facilitators: Salim S. Abdool Karim & Kathy Hinson

8:00 AM to 10:15 AM	Site Management: Budgeting & Funding, Staffing, Staff Retention & Incentives
10:15 AM to 10:45 AM	<b>BREAK</b>
10:45 AM to 12:00 PM	Role of PSRT in Safety Monitoring of MTN Studies ( <b>Connolly, Harwood</b> )
12:00 PM to 1:00 PM	<b>LUNCH</b>
1:00 PM to 2:45 PM	Adverse Event Reporting Overview & Scenario Discussions ( <b>Connolly, Harwood</b> )
2:45 PM to 3:15 PM	<b>BREAK</b>
3:15 PM to 4:45 PM	Preparation for MTN-015: HIV/AIDS Natural History & Concurrent WHO Treatment Guidelines ( <b>Riddler, International Investigator TBN</b> )
4:45 PM to 5:00 PM	Identification of Next Steps and Action Items



**Wednesday, May 23, 2007 – Study Coordinator Breakout**  
**Facilitators: Kaila Gomez & Anne Coletti**

8:00 AM to 10:15 AM	Participant Retention: What are we doing? What have we learned? What should we do in the future?
10:15 AM to 10:45 AM	<b>BREAK</b>
10:45 AM to 12:00 PM	Overview of DAIDS New Policies & Procedures
12:00 PM to 1:00 PM	<b>LUNCH</b>
1:00 PM to 2:45 PM	Adverse Event Reporting Overview & Scenario Discussions ( <b>Connolly, Harwood</b> )
2:45 to 3:15 PM	<b>BREAK</b>
3:15 PM to 4:45 PM	Adherence to Product use: What are we doing? What have we learned? What should we do in the future?
4:45 PM to 5:00 PM	Identification of Action Items and Next Steps
7:00 PM	Reception

### Thursday, May 24, 2007 – Regional Meeting Wrap-up

8:00 AM to 8:30 AM	Welcome and Review of Meeting Objectives ( <b>Hillier</b> )
8:30 AM to 9:00 AM	Report back from Clinician Session (speaker to be named)
9:00 AM to 9:30 AM	Report back from Laboratory Session (speaker to be named)
9:30 AM to 10:00 AM	Report back from Study Coordinator Session (speaker to be named)
10:00 AM to 10:30 AM	Report back from Community Session (speaker to be named)
10:30 AM to 11:00 AM	<b>BREAK</b>
11:00 AM to 11:30 AM	Report back from Pharmacy Session
11:30 AM to 12:00 PM	Summary & Wrap-up
12:00 PM to 1:00 PM	<b>LUNCH</b>
1:00 PM to 1:30 PM	MTN-001 Session: Introduction to MTN-001 ( <b>Hendrix</b> )
1:30 PM to 2:00 PM	Overview of Protocol Development
2:00 PM to 2:30 PM	Timeline & Implementation ( <b>Noguchi/FHI</b> )
2:30 PM to 3:00 PM	Introduction to SCHARP ( <b>Masse/Cianciola</b> )
3:00 PM to 3:30 PM	<b>BREAK</b>
3:30 PM to 4:30 PM	Review of Activation Requirements
4:30 PM to 5:00 PM	Wrap-up and Next Steps

### Thursday, May 24, 2007 –Community/Communication Planning

1:00 PM to 6:00 PM	Community Breakout ( <b>White</b> )
1:30 PM to 4:30 PM	How to Review a Protocol and Provide Feedback ( <b>White/Ukpong</b> )
4:30 PM to 6:00 PM	Wrap-up, Feedback and Certificates ( <b>Ukpong/White</b> )

### Thursday, May 24, 2007 –MTN-015 Operational Walkthrough

8:00 AM to 8:30 AM	Welcome and Introductions
8:30 AM to 9:00 AM	Purpose and Objectives of the Meeting
9:00 AM to 9:30 AM	MTN-015 Protocol Overview and Q&A
9:30 AM to 11:00 AM	MTN-015 Visits and Procedures
11:00 AM to 12:00 PM	Operational Issues Associated with MTN-015 Specimen Collection
12:00 PM to 1:00 PM	<b>LUNCH</b>
1:00 PM to 2:00 PM	Operational Issues with Potential Impacts on Participant Confidentiality: Issues, Challenges and Operational Solutions
2:00 PM to 4:30 PM	Data Collection and Management
4:30 PM to 5:00 PM	Review of Key Decisions, Recommendations, Pending Questions and Action Items