

## MICROBICIDES 2008 CONFERENCE PROGRAMME

**Saturday, 23 February 2008**

### Workshops

**NIH / OAR Grantsmanship Workshop for Junior Level and New Investigators in Conjunction with Microbicides 2008**

**Venue: Hotel Hyatt Regency**

**08:30 onwards Registration in the Regency Ballroom I and II**

10:00 - 10:30	<b>Welcome and introductory Remarks</b>	Dr. Jack Whitescarver, Associate Director for AIDS Research and Director, Office of AIDS Research (OAR), National Institutes of Health (NIH) Dr.Nomita Chandhiok, Deputy Director General, Indian Council of Medical Research (ICMR) Professor Nirmal K. Ganguly, Distinguished Biotechnology Fellow and Advisor, Translational and Health Science and Technology Institute.
10:30 - 10:45	<b>Role of Programme, Review and Grants Management in the Grant's Process</b>	Dr. Susan Plaeger, National Institute of Allergy and Infectious Diseases (NIAID), NIH
10:45 - 11:30	<b>The Process of Obtaining Funding</b>	Dr. Beth Fischer, University of Pittsburgh
11:30 - 11:45	<b>BREAK</b>	
11:45 - 13:00	<b>The Process of Obtaining Funding (Continued)</b>	
13:00 - 14:00	<b>LUNCH BREAK</b>	
14:00 - 14:30	<b>Components of a Successful Grant</b>	Dr. Beth Fischer, University of Pittsburgh
14:30 - 14:45	<b>NIH Electronic Submission Tips for International Applicants</b>	Dr. R. V. Srinivas, Center for Scientific Review (CSR), NIH
14:45 - 15:45	<b>Mock Study Section Meeting</b>	NIH Staff: Drs. Eugene Baizman, Sujata Vijn and Geetha Bansal, NIAID; Ms. Katherine Davenny, National Institute on Drug Abuse (NIDA); and Dr. Willo Pequegnat, National Institute of Mental Health (NIMH)
15:45 - 16:00	<b>BREAK</b>	
16:00 - 16:10	<b>Funding Opportunities from NIH for International Investigators</b>	Dr. Opendra Sharma, NIAID, NIH
16:10 - 16:25	<b>Guidelines and Procedures for International Collaboration Projects from ICMR's Point of View</b>	Dr. Mukesh Kumar, ICMR
16:25 - 16:40	<b>Opportunities for Collaborations with NIH-Funded Centers for AIDS Research</b>	Dr. Jeanne McDermott, Forgarty International Center (FIC), NIH, Dr.Kenneth Mayer, Center for AIDS Research (CFAR) at Lifespan/Tufts/Brown
16:40 - 16:55	<b>Positioning Yourself for Success</b>	Dr. Sharon Hillier, University of Pittsburgh
16:55 - 17:50	<b>Round Table Discussion and Q&amp;A</b>	NIH and ICMR/ Department of Biotechnology (DBT) Staff.
17:50	<b>Concluding Remarks</b>	Dr. Robert Eisinger, OAR, NIH

**OAR / FIC / OBBSR - Workshop for Junior Social Scientists: Integration of Social Science Research Clinical Trials**

**Venue: Hotel Hyatt Regency**

09:00 - 17:00	<b>Orientation to Workshop (20 minutes)</b>	a. Introductions b. Review Objectives and Agenda c. Caveats
	<b>Clinical Trials: Pressing Questions and Limitations (30 minutes)</b>	<b>Primary Presenters: Lut Van Damme and Jennifer Deese</b> 1.Fundamentals of clinical trials research 2.Lingering questions for microbicide clinical trials and the potential role of social science research 3.Challenges to integration
	<b>Review of Methods (1hour)</b>	<b>Primary Presenter: Robert Pool</b> 1.Review of a range of data collection methods - from qualitative to quantitative 2.Validating measures in new contexts 3.Implications for data management
	<b>Theoretical perspectives (30 minutes)</b>	<b>Primary Presenter: Kate Morrow</b> Trainer to review selected number of behavioral theories that have informed previous Microbicide SSR research and emphasize increasing emphasis placed on beginning with a theoretical framework.
	<b>Design (1 hour)</b>	<b>Primary Presenter: Susan Rosenthal</b> Trainer will provide an overview of key decision points when designing a new SSR study. They include: 1. Writing measurable research questions 2. Linking research questions to data sources 3. Group work
<b>LUNCH BREAK AND GROUP WORK</b>		
	<b>Analysis (1hour 30 minutes)</b>	<b>Primary Presenters: Mark Weaver (quantitative analysis)</b> 1.Overview of design issues related to statistical analysis 2.Overview of analysis methods particularly relevant for data from longitudinal trial <b>Primary Presenters: Betsy Tolley (qualitative analysis)</b> 3.Presentation of one approach to analyzing qualitative data with hands-on experience coding and interpreting text
	<b>Research dissemination: (30 minutes)</b>	<b>Primary Presenter: Beth Robinson</b> 1.Coordinating publications of integrated clinical trial/social science research 2.Authorship - regulations and expectations, need to negotiate up from 3.Standard formats for different journals - essential elements for a publishable paper 4.Dissemination to the broader community

	<b>Budgets</b>	<p><b>Primary Presenter: Bill Kapogiannis</b> NIH representative to review budget guidelines and process. Emphasize development of field budgets that reflect research design decisions.</p> <p><b>References</b> <span style="float: right;">NIH</span> Qualitative Methods in Health Research: Opportunities and Considerations in Application and Review 2001 NSF Workshop on Interdisciplinary Standards for Systematic Qualitative Research <a href="http://www.wjh.harvard.edu/nsfqual/">http://www.wjh.harvard.edu/nsfqual/</a> accessed 2004. <b>Qualitative Methods in Public Health: Ulin, Robinson &amp; Tolley</b></p>
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**Sunday, 24 February 2008**

**08:00 – 15:30 REGISTRATION AT SWIMMING POOL LAWNS, ASHOK HOTEL**

**Workshop**

**M2008 Pre-Conference Workshop on "Health Advocacy" (Hosted by AMAG, GCM, INN, NCHI, PWN+)**

**Venue: Jacaranda Hall, India Habitat Centre**

<b>09:00 - 11:10</b>	<b>Morning Session</b>	<p>The M2008 Pre-Conference will begin with a set of plenary talks designed to provide a status report on the microbicide science and advocacy, including an introduction to the history of the field, a snapshot of where we are now, and an introduction to the debates and issues that participants are likely to encounter in the M2008 Conference.</p> <p><b>Introduction</b> <span style="float: right;"><b>Speaker:</b></span> <b>Dazon Dixon Diallo, SisterLove, Inc.</b></p> <p><b>State of the Field: Microbicide Science and Trials</b> <b>Speaker: Dr. Sharon Hillier, Microbicide Trials Network (MTN)</b></p> <p><b>State of the Field: Advocacy, Ethics and Access</b> <b>Speaker: Manju Chatani (AMAG) &amp; Anna Forbes (GCM)</b></p> <p><b>Our Host Country: Microbicide and Female Condom Advocacy in India</b> <b>Speaker: Paramita Kundu (GCM)</b></p> <p><b>Microbicide Resources: An introduction to Tools, Actors, and where to Go for information</b> <b>Speaker: Arwa Meijer (GCM) &amp; Bindiya Patel (GCM)</b></p> <p><b>Closing Remarks &amp; Description of the Break-out Sessions</b> <b>Speaker: Lori Heise (GCM)</b></p>
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**11:10 - 11:30 Morning Coffee / Tea Break**

<b>11:30-13:15</b>	<b>Break-Out Sessions</b>	<p><b>1. Knowledge Session: Microbicides Basics</b> <span style="float: right;">This</span> This session will cover the basics of microbicides: products, mechanisms of action, the clinical research process and an introduction to ethical issues in HIV prevention trials. <b>Facilitators: Bindiya Patel (GCM) &amp; Dr. Kamini Walia, Indian Council of Medical Research (ICMR)</b></p> <p><b>2. Knowledge Session: An Introduction to ARV-based Microbicides &amp; Resistance</b> This session will cover the new line of ARV-based microbicide candidates entering the research pipeline and the rationale of exploring such candidates. The session will also include an overview of the issues unique to ARV-based products, including resistance, and a discussion of questions the field has yet to answer. <b>Facilitators: John Mellors (MTN), Jeanne Marrazzo (MTN) &amp; Lori Heise (GCM)</b></p> <p><b>3. Skills-building: Advocacy Training</b> This session will present a structured view of advocacy and the need for advocacy campaigns. It will introduce participants to various strategies and tools for building campaigns at local, regional and national levels. This session will also focus on why it is important to engage in advocacy and not just awareness-raising. <b>Facilitators: Brigit Haire, Australian Federation of AIDS Organization (AFAO), Manju Chatani (AMAG) and Katie West (GCM)</b></p> <p><b>4. Skills-building session: When Trials End - The Role of Advocacy</b> What makes a successful trial? What are some of the reasons a trial might be stopped? What can we learn from recent trial results and closures? We will discuss recent trial closures and what role advocates can have in helping communities and the public interpreting the results. <b>Facilitators: Mitzy Gafaos, Microbicide Development Programme (MDP), Anna Forbes (GCM) &amp; Morenike Ukpong, Nigerian HIV Vaccine and Microbicides Advocacy Group (NHVMAG)</b></p>
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**13:15-14:00 LUNCH**

<b>14:00-15:00</b>	<b>Closing Session: Getting the Most out of the M2008 Conference</b>	<p>How to Maximize your Conference Experience Networking Free for All Burning Questions &amp; Answers</p>
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**AMD Symposium - Industrializing Microbicides**

**Venue: Cocktail Lounge, Hotel Ashok**

<b>Scientific Program &amp; Faculty</b>	<b>Co Chairs: Polly Harrison, Alliance for Microbicide Development</b> <b>Kevin Whaley, Mapp Biopharmaceutical</b>	
<b>09:00 - 10:00</b>	<b>Session 1: Workshop: GLP Toxicology Studies</b>	<p><b>Items to be addressed by speakers:</b></p> <ol style="list-style-type: none"> <li>1. GLP Toxicology summary of candidate microbicides</li> <li>2. Discussion of challenges encountered by sponsors</li> </ol> <p><b>Moderator: Liza Solomon (AMD)</b></p> <p>Panelists:</p> <ol style="list-style-type: none"> <li>1. Summary of Toxicology/Formulation Workshop, Jeremy Nuttall (IPM)</li> <li>2. Preclinical Safety: A Case Study of BufferGel, Thomas Moench (ReProtect)</li> </ol>
<b>10:00 - 11:00</b>	<b>Session 2: Manufacturing Chemical Microbicides</b>	<p><b>Items to be addressed by speakers:</b></p> <ol style="list-style-type: none"> <li>1. What are current manufacturing capabilities for candidate microbicides?</li> </ol> <p><b>Moderator: Sidney Rubinstein (Regulatory Compliance Initiatives)</b></p> <p>Panelists:</p> <ol style="list-style-type: none"> <li>1. Overview of Potential Manufacturers for Chemical Microbicides, James Carter (RCI)</li> <li>2. Vikas Narendra (Ind Swift Laboratories Limited)</li> <li>3. Amit Rajan (Alkem Laboratories)</li> <li>4. Tarun Patel (Shasun Chemicals and Drugs Ltd)</li> </ol>

11:00 - 12:00	<b>Session 3: Manufacturing Biological Microbicides</b>	<b>Items to be addressed by speakers</b> 1. What are current manufacturing capabilities? 2. What are current capabilities for formulation of biologics? <b>Moderator: Kevin Whaley (Mapp)</b> Panelists: 1. Production in Bacteria, Oliver Hartley (University of Geneva) 2. Microbicide Releasing Commensals, Laurel Lagenaur (Osel) 3. Production in Plants, Kevin Whaley (Mapp) 4. Manufacturing of Biologics in India, Viloo Morawala-Patell (Avesthagen)
12:00 - 13:00	<b>LUNCH</b>	
13:00 - 14:00	<b>Session 4: Intellectual Property Considerations</b>	<b>Items to be addressed by Speakers:</b> 1. What is the IP position of most candidate microbicides in India? 2. What are likely IP agreements? <b>Moderator: Anatole Krattiger (Arizona State University)</b> Panelists: 1. Intellectual Property Management in Health, Anatole Krattiger (ASU) 2. Intellectual Property Management in India, Kanikaram Satyanarayana, (IP Unit, Indian MRC) 3. Dr. Venugopal
14:00 - 15:00	<b>Session 5: Regulatory Considerations</b>	<b>Items to be addressed by speakers:</b> 1. What is the regulatory status of most candidate microbicides in India? 2. What are likely regulatory challenges and opportunities? <b>Moderators: Tim Farley (WHO)</b> Panelists: 1. Regulating Microbicides, Tim Farley (WHO) 2. Trends in Pharmaceuticals Regulations, Alan Stone (IWGM)

### Rectal Microbicides Update Symposium

Venue: Banquet Hall, Hotel Ashok

Organized by AMFAR, The UCLA AIDS Institute, and The University of Pittsburgh School of Medicine

09:00-13:00	<b>Symposium Objectives</b>	An overview of recent advances in rectal microbicide development Improvements in applicator design The role of nonclinical studies in screening rectal microbicide candidates An update on advocacy directed towards increasing funding for rectal microbicides	
	<b>Scientific Programme</b>	Ian McGowan MD PhD	Symposium Overview
		Rowena Johnston PhD	amfAR funded research
		Charlene Dezzutti PhD	Nonclinical evaluation
		Dorothy Patton PhD	Non human primate studies
		Ross Cranston PhD	The anal canal as a target for HIV
		Peter Anton MD	Phase 1 rectal microbicide studies
		Craig Hendrix MD	Rectal specific microbicides
		Alex Carballo-Diequez PhD	Product acceptability
		Jim Picket	Rectal microbicide advocacy

### NIH / OAR Workshop on ARV and ARV Resistance: How Does This Inform the Microbicides Research Agenda?

Venue: Banquet Hall, Hotel Ashok

Time	Speaker	Presentation Title
13:00-13:30	Dr. Joseph Romano	ARVs in Microbicides Pipeline and Status of Testing
13:30-14:00	Dr. Bonaventura Clotet	What is ARV Resistance?
14:00-14:30	Dr. Craig Hendrix	Pharmacology of ARV Resistance
14:30-15:00	Dr. John Mellors	Key Issues in ARV-based Microbicide Clinical Studies
15:00-15:30	Professor Sally Blower	Modelling of ARV Resistance in Microbicides Trials
15:30-16:00	Dr. Chidi Nweneke	Impact of Potential Resistance on Conducting ARV-Based Microbicide Clinical Trials: Community Perspective
16:00-17:00		Panel Discussion (Questions raised in each talk and questions from the audience) PANEL: 6 speakers

### 17:30 – 19:00 OPENING CEREMONY - Convention Hall, Hotel Ashok

**Chief Guest** Dr. Anbumani Ramadoss - Honourable Union Minister for Health and Family Welfare

**Cultural Programme** Aditi Mangaldas Dance Company - Drishtikon Dance Foundation

### 19:00 – 21:00 WELCOME RECEPTION - Lilypool Lawns, Hotel Ashok

## Monday, 25 February 2008

Convention Hall (Part I & II)					
08:15 – 09:55	<b>Plenary Lecture</b>	Latest understanding of HIV sexual transmission T. Hope	Approaches to integration of behavioral research into regulatory phase I, II, and III studies of microbicides Mensch	B.	Microbicide and women's health and empowerment L. Mataka
	<b>Chairs: G. Ramjee</b>				
	<b>B. Saxena N. Chandhiok</b>				
10:00 – 11:00special symposium	<b>Plenary Lecture</b>	Opportunity and challenges of microbicide research in developing countries Detels	N.K. Ganguly	S. S. Abdool Karim	R.
<b>Chairs: J. Darbyshire H. Gabelnick</b>					
11:00 – 11:20	<b>MORNING TEA/COFFEE BREAK</b>				
11:20 – 12:15	Keynote address/ Symposia	<b>TRACK A (Convention Hall Part I)</b>	<b>TRACK B (Convention Hall Part II)</b>	<b>TRACK C (Banquet Hall at 3rd Floor)</b>	<b>TRACK D (Cocktail Lounge at 3rd Floor)</b>
		<b>Symposium</b>	<b>Key Note Address</b>	<b>Key Note Address</b>	<b>Key Note Address</b>
		<b>Drug Discovery:</b> Chair: G. Doncel Co-Chair: A. T. Haase	Chair: T. Farley Co-chair: Ben Masse	Chair: B. Tolley Co-Chair: N. Mawar	Chair: R. Bhattacharya Co-Chair: Bindhya Patel



		HIV-1 Integration: A target for microbicides?	Stability of mucosal cytokine profiles and mononuclear lymphocyte phenotype following rectal administration of UC-781 microbicide gel in a phase I safety assessment	What predicts adherence in a safety trial – is it generalizable beyond the trial setting?	Community perceptions of vaginal microbicides phase III trial in rural SW Uganda
		<b>KI Terrazar-Aranda (571)</b>	<b>D.D. Cho (427)</b>	<b>E.E. Tolley (590)</b>	<b>W. Nalukene (324)</b>
<b>13:15 – 14:15</b>	<b>LUNCH BREAK AT SWIMMING POOL LAWNS, HOTEL ASHOK (Exhibitions)</b>				
	<b>Room no 479 at 4th Floor</b>				
<b>13:15 – 14:15</b>	<b>NIH/OAR Lunch Break Session - Hotel Ashok</b>	<b>Basic and Preclinical Microbicide Science (J. Turpin and C. Deal)</b>			
		<b>Clinical Microbicide Science (R. Black and C. Deal)</b>			
		<b>TRACK A (Convention Hall Part I)</b>	<b>TRACK B (Convention Hall Part II)</b>	<b>TRACK C (Banquet Hall at 3rd Floor)</b>	<b>TRACK D (Cocktail Lounge at 3rd Floor)</b>
<b>14:15 – 15:30</b>	<b>Abstract Session</b>	<b>Advances in formulations</b>	<b>Findings from Phase I and II Trials</b>	<b>Behavioral and social science research tools</b>	<b>Community involvement in microbicide trials</b>
		Chair: K.K. Bhutani	Chair : M. Roy	Chair: A. Carballo Dieguez	Chair: K. Dickson
		Co-chair: B. Herold	Co-Chair : W. EL Sadr	Co-chair: K. Mungambe	Co Chair: R. Pool
		<i>Development of a vaginal ring device for long-term administration and pre-clinical efficacy testing of UC781 In macaques</i>	<i>A phase I/II RCT on the safety, tolerance and acceptability of the invisible condom®, in healthy volunteers in Cameroon</i>	<i>Emic perspectives on microbicides and sexual health: a new approach to acceptability</i>	<i>Awareness of university teachers about microbicides and HIV/AIDS, in Karachi, Pakistan .</i>
		<b>K. Malcolm (207)</b>	<b>R.F. Omar (86)</b>	<b>C. Montgomery (403)</b>	<b>A. Shaikh (185)</b>
		<i>Formulation characteristics have a measurable impact on the Anti-HIV activity of Dapirivine</i>	<i>SAVVY (C31G) vaginal gel for prevention of HIV infection: a randomized controlled trial in Nigeria</i>	<i>Challenges implementing behavioral research in microbicides clinical trials</i>	<i>Creating research literacy in research communities: using road shows to raise awareness in the Umkhanyakude District of Northern KwaZulu Natal</i>
		<b>P.L. Manlow (226)</b>	<b>P.J. Feldblum (142)</b>	<b>S. Abbott (641)</b>	<b>N. Mncwango (349)</b>
		<i>Expression of rantes derivatives In lactobacilli: A novel strategy for the development of vaginal microbicides</i>	<i>Clinical safety and tolerability assessment of an anti-HIV dapivirine vaginal microbicide gel (GEL-002)</i>	<i>Menstrual cycle history taking – the challenge and lesson learned during conduct of a phase I microbicide (vivagel TM) safety trial in Kisumu, Kenya</i>	<i>The missing chapter of the microbicide development strategy: Addressing the priority, gaps and barriers to full civil society engagement</i>

		<b>L. Vangelista (235)</b> <i>A biodegradable nanoparticle drug delivery system of psc-rantes for the prevention of HIV</i>	<b>S. Smythe (546)</b> <i>Pharmacokinetic assessment of an anti-HIV dapivirine vaginal microbicide gel (GEL-002)</i>	<b>M.K. Momanyi (428)</b> <i>Improving behavioral data collection with the use of state-of-the-art information technology tools</i>	<b>A. Forbes (577)</b> <i>Putting women at the centre of advocacy efforts: Lessons learned from South Africa</i>
		<b>A.S. Ham (406)</b> <i>Effect of water soluble polymers on NNRTI UC -781: Beta – Cyclodextrin complex Formation.</i>	<b>A. Nel (563)</b> <i>Preliminary results from a pharmacokinetic study of the candidate vaginal microbicide agent 1% tenofovir gel</i>	<b>A. Ventuneac (629)</b>	<b>N.M. Mcanyana (396)</b>
		<b>H. Yang (609)</b> <i>Efficacy studies of a formulated octylglycerol lipid in the pigtailed macaque model: Trichomonas vaginalis and Chlamydia trachomatis</i>	<b>J.L. Schwartz (610)</b> <i>Safety and acceptability of daily and coitally dependent use of 1% tenofovir over six months of use</i>		
		<b>D.L. Patton (60)</b>	<b>S.L. Hillier (655)</b> <i>Unacceptable side effects of a hyperosmolar vaginal microbicide in a phase I trial</i>		
			<b>C. Lacey (527)</b>		
<b>15:30 – 16:00</b>	<b>AFTERNOON TEA/COFFEE BREAK</b>				
		<b>TRACK A (Convention Hall Part I)</b>	<b>TRACK B (Convention Hall Part II)</b>	<b>TRACK C (Banquet Hall at 3rd Floor)</b>	<b>TRACK D (Cocktail Lounge at 3rd Floor)</b>
<b>16:00 – 17:30</b>	<b>Panel Discussion/ Round Table/Abstracts</b>	<b>Round Table</b> <b>DBT sponsored</b> <b>Critical gaps in early microbicide development</b>	<b>Panel Discussion</b> <b>NACO sponsored</b> <b>Impact of other HIV prevention trials</b>	<b>Abstract</b> <b>Acceptability</b>	<b>Abstract</b> <b>Managing Stakeholder Expectations of Trial Results</b>
		Chair : M.K. Bhan	Chair : S. Rao	Chair: S. Sahay	Chair: D.D. Diallo
		Moderator: J. Turpin	Facilitator: V. Miller	Co – Chair: W. Stones	Co-chair: A. Kundu
		<b>Panelists:</b>	<b>Panelists:</b>	<i>A contextual model of microbicide acceptability</i>	<i>Managing expectations and unexpected results: The role of the microbicides media and communication initiative (MMCI).</i>

		<i>In vitro</i> models and biomarkers of safety <b>R. Fichorova</b>	Overview <b>W. Cates</b>	<b>K. Morrow (557)</b> <i>Cleansing, curing and exciting: unanticipated attributes of a microbicide gel in the MDP 301 trial, South Africa</i>	<b>D. Baron (438)</b> <i>Community misunderstandings arising from simultaneous premature closure of Conrad's Cellulose Sulfate trial and scheduled completion of Population Councils phase III Carraguard trial.</i>
		<i>In vivo</i> models of safety <b>M. Keller</b>	Diaphragms <b>N. Padian</b>	<b>S.P. Seoka (540)</b> <i>An assessment of the acceptability of PRO 2000/5 microbicide gel in the MDP 301 trial in Johannesburg</i>	<b>P.N. Mthembu (510)</b> <i>Microbicide research in Nigeria - Other than scientific successes.</i>
		Humanized animal models <b>V. Garcia</b>	HSV-2 <b>A. Ouedraogo</b>	<b>J. Dhooke (391)</b>	<b>L.K. McNeil (513)</b>
		NHP models <b>C. Cheng-Mayer</b>	Male Circumcision <b>C. Hankins</b>	<i>Gel or suppositories? Results of a rectal microbicide preference trial</i>	<i>Apples And Oranges? Interpreting success from contraceptive and HIV prevention research</i>
				<b>A. Carballo-Diequez (210)</b> <i>Use of the diaphragm instead of condoms in the MIRA trial</i>	<b>C. Watts (518)</b>
				<b>A. van der Straten (413)</b> <i>Acceptability and adherence: findings from phase II study of a candidate vaginal microbicide, praneem polyherbal tablet in Pune, India.</i>	
				<b>N. S. Joglekar (467)</b>	

		<b>TRACK A (Convention Hall Part I)</b>	<b>TRACK B (Convention Hall Part II)</b>	<b>TRACK C (Banquet Hall at 3rd Floor)</b>
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17:30 – 18:30	Satellite Symposia/ Workshop	<b>Satellite Symposium dosage forms for microbicides</b> <b>New</b>	<b>Report-Back Session</b>	<b>Skills Building Session</b>
		Chair : S. Gupta		
		Co-Chair : J. Cohen		
		<b>Facilitator: J. Romano</b>	<i>Development adherence meeting</i>	The Media—microbicide friend or foe? Training for participants, researchers CAB and community members
			Report from AMD	
		<b>Speakers</b>	<b>B. Tolley</b>	<b>Facilitators:</b>
		<i>Rings</i> <b>K. Malcolm</b>	<i>Making HIV trials work for women</i>	<b>J. Pickett</b> <b>M. Ukpog</b>
	Report from UNAIDS			
	<b>C. Hankins</b>			
	<i>Films and rectal formulations</i> <b>L. Rohan</b>			
	<i>Tablets and Capsules</i> <b>S. Garg</b>			

18:30 – 20:30	<b>POSTER RECEPTION AT HARD COURT AREA, HOTEL ASHOK</b>			
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<b>Tuesday, 26 February 2008</b>				
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08:15 – 10:00	Plenary	Convention Hall (Part I & II)			
	Chairs : A. Surolia S. Solomon J. Whitescarver	<i>Update on the microbicide pipeline: current and emerging candidates</i> <b>C. Kelly</b>	<i>Update from clinical trials of microbicide effectiveness</i> <b>S. Hillier</b>	<i>Male sexuality and HIV risk</i>	
				<b>R. Varma</b>	

10:00 – 10:30	<b>MORNING TEA/COFFEE BREAK</b>			
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		<b>TRACK A (Convention Hall Part I)</b>	<b>TRACK B (Convention Hall Part II)</b>	<b>TRACK C (Banquet Hall at 3rd Floor)</b>	<b>TRACK D (Cocktail Lounge at 3rd Floor)</b>
10:30 – 11:30	Keynote address/ Symposia/Panel Discussion	<b>Symposium</b>	<b>Panel Discussion</b>	<b>Key Note Address</b>	<b>Key Note Address</b>
		<i>New approaches to microbicide candidates</i>	<i>Clinical Safety studies of vaginal microbicides: What do we need to know? What have we learned?</i>	<i>Microbicide formulations and delivery systems: behavioral perspectives</i>	<i>Modeling the impact of microbicide introduction</i>
		Chair : C. P. Puri	Chair : R. Misra	Chair : S. Bharat	Chair : L. Kant
		Co-Chair : B. Wighdhal	Co-chair- S.D. Seth	Co-chair: G. Brown	Co-chair: R. Hayes
		<b>Facilitator: B Harwood</b>	<b>Panelists:</b>	<b>Speaker:</b>	<b>Speaker:</b>
	<i>Gene silencing</i> <b>B. Ramratnam</b>	<i>Overview of Clinical Safety Studies</i> <b>J. Weber</b>	<b>K. Morrow</b>	<b>S.Blower</b>	
	<i>Enhanced innate immunity</i>	<b>J. Schwarz</b>			

		<b>K. Rosenthal</b>	<b>S. Joshi</b>		
		<i>Pyrimidinediones: molecules with dual mechanism of action</i>			
		<b>B. Buckheit</b>			
		<b>TRACK A (Convention Hall Part I)</b>	<b>TRACK B (Convention Hall Part II)</b>	<b>TRACK C (Banquet Hall at 3rd Floor)</b>	<b>TRACK D (Cocktail Lounge at 3rd Floor)</b>
11:45 – 12:45	Abstract Session	Innovative approaches	Lessons learned from cohort studies	Community Engagement in Trials	Engaging a broader audience in Microbicide advocacy
		Chair : R. Eisinger	Chair : S. Mehendale	Chair: N. Morar	Chair: R. Battacharya
		Co-Chair : S. Sinha	Co-Chair: R. Ridzon	Co-Chair: R. White	Co-Chair: S. Walker

		<i>Targeted delivery of Sirna to T Cells inhibits HIV replication In a humanized mouse model</i>	<b>Key Note Address :</b> Population Council : Results of Phase III Carraguard Trial	<i>Community vs researcher's perspectives on community demand from trials</i>	<i>An International and multi-disciplinary approach to rectal microbicide advocacy</i>
		<b>P. Shankar (657)</b>	<b>E. Johansson</b>	<b>M.O. Ukpong (123)</b>	<b>J.W. Pickett (308)</b>
		<i>Endogenous microbicides in the human female reproductive tract: innate anti-HIV-1 activity in epithelial cell secretions</i>	<i>Contraceptive provision and choices among women participating in the Caprice 004 phase IIb tenofovir gel trial in urban and rural KwaZulu-Natal, South Africa</i>	<i>Issues affecting understanding of key informed consent messages in the MDP 301 trial in Mazabuka, Zambia</i>	<i>Rectal microbicide advocacy and anal intercourse in a homophobic nation: The problems of the sexual act as sexual orientation</i>
		<b>M. Ghosh (173)</b>	<b>C. Baxter (474)</b>	<b>S.N. Kalumbilo (536)</b>	<b>N. Z. Haniff (270)</b>
		<i>Ex vivo effect of microbicides on HIV-1 integration in intraepithelial langerhans and TCells of the human vagina –</i>	<i>Attitudes toward female and male condoms among South African women university students: Predictive factors and their implications for microbicide acceptability</i>	<i>Strategies implemented to increase participant retention in a community based HIV prevention efficacy trial in Durban, South Africa.</i>	<i>Building the platform for HIV prevention for adolescent girls</i>
		<b>F. Hladik (640)</b>	<b>J.A. Smit (437)</b>	<b>S. Gappoo (135)</b>	<b>M. Brody (465)</b>
		<i>Local modulation of HIV infection by non-HIV microbes in human tissues</i>	<i>Effect of HSV-2 suppressive therapy on prevention of HIV acquisition (HPTN 039)</i>	<i>Socio-behavioral and community activities for an oral HIV prevention prep clinical trial: a multi-disciplinary approach</i>	<i>Vital Voices: HIV-positive women's involvement in microbicide development</i>
		<b>LB. Margolis (604)</b>	<b>C.L. Celum (309)</b>	<b>A.L. Corneli (588)</b>	<b>L. D. Binder (353)</b>
<b>13:00 – 14:00</b>	<b>LUNCH BREAK AT SWIMMING POOL LAWNS, HOTEL ASHOK (Exhibitions)</b>				
	<b>Room no 479 at 4th Floor</b>				
<b>13:00 - 14:00</b>	<b>NIH/OAR Lunch Break Session - Hotel Ashok</b>	<b>Behavioral Science in Microbicide Clinical Trials</b>			
		<b>Convention Hall Part I</b>	<b>Convention Hall Part II</b>		
<b>14:00 – 15:30</b>	<b>Abstract Session</b>	<b>Evaluation of candidates</b> Chair : G.P. Talwar	<b>Cross Track B, C &amp; D</b>		
		<b>Co-Chair : R. Veazey</b> <i>Detecting rectal epithelial disruption using radioisotopes: a simple test to identify potential HIV microbicide toxicity</i>	<b>When clinical trials end: challenges, experiences and lessons learned</b> Chair : M. Warren Moderator: L. Heise		
		<b>E. Fuchs (209)</b>	<b>Speakers:</b>		

		Colonic luminal and tissue distribution of lymphocytes and HIV-sized particles suspended in seminal plasma in healthy men following simulated receptive anal intercourse	Lessons from managing the closure of multi-country HIV prevention trials <b>L. Van Damme</b>		
		<b>S. Nimmagadda (441)</b>			
		Characterization of vaginal transmission of simian human immunodeficiency virus (SHIV) to evaluate the efficacy of microbicides in nonhuman primates	Translating trial closure – lessons from working with international advocates <b>M. Chatani</b>		
		<b>R. Pal (351)</b>			
		Fully recombinant chemokine analogues provide complete protection in the macaque vaginal challenge model	All trial endings are local – lessons learned from trial closures in South Africa <b>Gita Ramjee</b>		
		<b>O. Hartley (286)</b>			
		Analysis of mucosal cytokines and innate factors over ovulatory cycles in female pigtailed macaques: baseline and toxicity evaluation	Discussion (30 mins)		
		<b>S.T. Butera (582)</b>			
		Anti-HIV activity of rantes analogues in human genital tissue			
		<b>P.S. Fletcher (282)</b>			
		Development of a novel in vitro assay to evaluate microbicide products in a layered, polarized configuration			
		<b>B.E. Lai (561)</b>			
15:30 - 16:00	AFTERNOON TEA/COFFEE BREAK				

		Convention Hall Part I	Convention Hall Part II			
16:00 – 17:30	Panel Discussion	Criteria to enable rational microbicide selection for clinical efficacy testing	Establishing the Standard Of Care in HIV prevention trials			
		Chair : C. Kelly	Chair : F. Martinson			
		Co-chair : K. Walia	Co-chair : S. McCormack			
		Facilitator: R. Shattock	Facilitator: W. Kamau			
		<b>Panelists</b>	<b>Speakers</b>			
		J. Romano	<i>Interpretation and implementation of standard of care protocols</i> <b>K. Shapiro</b>			
		G. Doncel	<i>Trial coordinators response and perspective</i> <b>M. Gafos</b>			
		B. Herold				
		R. Veazey	<i>Clinical/researcher's response and perspective</i> <b>S. Mehendale</b>			
			<b>Discussion: (30 mins)</b>			
				<b>TRACK A (Convention Hall Part I)</b>	<b>TRACK B (Convention Hall Part II)</b>	<b>TRACK C (Banquet Hall at 3rd Floor)</b>
17:30 – 18:30	Symposia/ Workshop	<b>Late Breakers Session</b>	<b>Symposium</b>	<b>Social Science Working Group Launch</b>	<b>Roundtable</b>	
			<b>Moving microbicides into vulnerable populations</b>		<b>Microbicides and HIV+Women</b>	
		Chair : A Stone	Chair : Peter J. Donaldson		Chair : A. Yuvraj	
		Co-chair: S Joshi	Facilitator: C Hankins		Co-chair : S. Mellors	
		Title: Intravaginal Administration of 6% Cellulose Sulfate (CS) Gel Prevented Systemic Infection in RHESUS MACAQUES in a Multiple Dose R5/X4 Shiv Vaginal Challenge Model Author: Mohammed Saifuddin	<b>Speakers</b>	<b>Speakers</b>	<b>Panelists</b>	
			<i>Pregnant women</i> <b>R. Beigi</b>	<b>B. Tolley</b> <b>W. Stones</b> <b>N. S. Morar</b>	F. Welter R. S. Mbandlwa N. Morar P. Mabele B. Herold J. Sokhey	
		Title: Single Vaginal Exposure with Cell - Associated SIVmac251 Results in Rapid, Reproducible and Persistent Infection of Non Human Primates Author: Roger LE Grand A	<i>People who practice anal intercourse</i> <b>I. McGowan</b>		<b>Skills Building Session for Community Advisory Board</b>	
			<i>Adolescents</i> <b>K. Slack</b>		<b>M. Chatani and M. Ukpong</b>	

**19:00 – 22:00 CONFERENCE DINNER AT JHANKAR BANQUETS, ASIAD TOWERS**

**Wednesday, 27 February 2008**

<b>Convention Hall (Part I &amp; II)</b>				
<b>08:15 – 10:00</b>	<b>Plenary Lecture</b>	<i>How product characteristics and delivery may influence clinical trial design</i>	<i>"An Information- Motivation-Behavioral Skills Model of Microbicide Adherence".</i>	<i>Reproductive Health/HIV technologies research and introduction: lessons for microbicides policy and advocacy</i>
	<b>Chairs :S.K. Bhattacharya P. Harrison R. Paranjpe</b>	<b>C. Lacey</b>	<b>J. Fisher</b>	<b>H. Rees</b>

**10:00 – 10:30 MORNING TEA/COFFEE BREAK**

		<b>TRACK A (Convention Hall Part I)</b>	<b>TRACK B (Convention Hall Part II)</b>	<b>TRACK C (Banquet Hall at 3rd Floor)</b>	<b>TRACK D (Cocktail Lounge at 3rd Floor)</b>
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<b>10:30 – 11:30</b>	<b>Symposia Lecture/Abstract Session</b>	<b>Symposium</b> <b>Development of combinations</b>	<b>Symposium</b> <b>Microbicides and HIV positive women</b>	<b>Abstracts Session</b> <b>Role of men in microbicide use</b>	<b>Abstracts Session</b> <b>Community Involvement to Improve Clinical Trial Methods</b>
		Chair : T. Ramasami Co-Chair : T. Mertenskoetter	Chair : V. Muthuswamy Co-chair : W. Cates	Chair: A. Jafar Co-Chair: L. Paxton	Chair : P. Malavaripu Co-chair: K. Blanchard
		<b>Speakers</b> <i>Conceptual definition and criteria</i> <b>J. Lange (TBC)</b>	<i>Issues related to HIV positive women – what is so unique about safety?</i> <b>W. El Sadr</b>	<i>Exploring microbicide acceptability in terms of socio-cultural norms, relationships and product attributes in the Carraguard phase III trial in South Africa</i> <b>A.E. de Kock (552)</b>	<i>Reducing attrition in cohorts of young reproductive age women: An Indian experience</i> <b>V.C. Sekaran (252)</b>
		<i>Formulation challenges</i> <b>P. Kiser</b>	<i>HIV positive women and Community</i> <b>A. Forbes</b>	<i>Motivation and practical constraints in secret use of microbicides in Harare, Zimbabwe</i> <b>P. Musara (229)</b>	<i>Strategies to recruit and retain couples in a vaginal microbicides trial of PRO2000/5 in a rural community, SW Uganda</i> <b>V. Basajja (333)</b>
		<i>Induction of resistance</i> <b>J. Mellors</b>		<i>Partner involvement in gel use: the case of MDP trial participants in Zambia</i> <b>O. Mweemba (442)</b>	<i>Giving trial participants a voice! Experiences from the MDP 301 clinical trial site in the Umkhanyakude district of Northern Kabuli Natal.</i> <b>S. Buthelezi (348)</b>
				<i>Role of men in a phase III vaginal microbicide trial in SW Uganda</i> <b>R. Kawuma (332)</b>	<i>Impact of donor-imposed requirements and restrictions on standard of care in microbicide trials</i> <b>S. Philpott (424)</b>
				<i>Impact and disclosure of gel use and trial participation to male partners on gel adherence.</i> <b>J. Phillip (338)</b>	

		<b>TRACK A (Convention Hall Part I)</b>	<b>TRACK B (Convention Hall Part II)</b>	<b>TRACK C (Banquet Hall at 3rd Floor)</b>	<b>TRACK D (Cocktail Lounge at 3rd Floor)</b>
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<b>11:45 – 13:00</b>	<b>Abstract Session</b>	<b>RTIs and combinations</b>	<b>Recruitment, retention and adherence</b>	<b>Moving Microbicides into vulnerable populations: social science perspectives on theory, design &amp; measurement</b>	<b>Feedback Session</b>
		Chair : D. Mitra Co-chair : J. Lange	Chair : A. Coletti Co-Chair : R. Govinden	Chair: R.N. Gupta Co-Chair: N. Padian	Chair: N. Chandhiok Co-Chair: G. Ramjee
		<i>Reverse transcriptase inhibitors as potential colorectal microbicides</i> <b>C. Herrera (498)</b>	<i>Strategies for recruitment and retention of women in the HPTN 059 phase II expanded safety and acceptability study of the vaginal microbicide 1% tenofovir gel in Pune, India.</i> <b>S.S. Das (110)</b>	<i>Vaginal practices, microbicides, and HIV transmission - How important is the connection?</i> <b>A.M. Hilber (485)</b>	<i>Report back ICMR/WHO/CONRAD/PM Regulatory Meeting</i> <b>T. Farley</b>

		Better protection against HIV-1 infection in vitro with candidate microbicide compounds in combination.	Recruitment and retention in a vaginal microbicide efficacy trial: Experiences with HIV negative women living in discordant couple relationships in rural SW Uganda	Challenges and results of including 16-17 year old women in the Carraguard phase III efficacy trial	Confronting the "Evidence" in Evidence-Based HIV Prevention: Current Issues in Microbicides and Related Research organized by AMD and SFAF
	S.M. Schader (273)		M.J. Kasse (321)	S.A. Skoler (645)	Moderator: Judy Auerbach and Liza Solomon Panelists: Kim Dickson, Nancy Padian and Mitchell Warren
		Microbicide interference with TLR signaling in the presence of vaginal bacterial colonization	Adherence to gel and condom use among Women participants in a phase III microbicide trial of PRO2000/5 in rural SW Uganda	Strategies used by educated women to ensure their protection from HIV infection	
	R.T. Trifonova (634)	Functional evaluation of 2F5 monoclonal IgG, IgA and IgM Isotypes in preventing HIV-1 infection of mucosal explant tissue.	H.S. Luwugge (329) An analysis of varying measures of adherence among women enrolled in the Carraguard phase III trial	N. Morar (479) An evaluation of care and support of women who test HIV positive during the phase III Carraguard® trial in South Africa	
	K. Klein (653)		S.A. Littlefield (533) A comparison between self-reported condom use and presence of spermatozoa using TV in pouch and wet mount, among women enrolled in the phase III Carraguard clinical trial in Cape Town	S. Patel (287) Not just participants recognizing the critical need for sex worker voices in microbicide research and development.	
			F.P. Gopolang (520)	M. Seshu (419)	
13:00 – 14:00	<b>LUNCH BREAK AT SWIMMING POOL LAWNS, HOTEL ASHOK (Exhibitions)</b>				
		<b>Room no 479 at 4th Floor</b>			
13:00 - 14:00	NIH/OAR Lunch Break Session-Hotel Ashok	Community Participation in Clinical Trials and Ethics Issues (K. Davenny, J. McDermott, B. Kapogiannis)			
		<b>TRACK A (Convention Hall Part I)</b>	<b>TRACK B (Convention Hall Part II)</b>	<b>TRACK C (Banquet Hall at 3rd Floor)</b>	<b>TRACK D (Cocktail Lounge at 3rd Floor)</b>
14:00 – 15:30	Abstract Session/ Panel Discussion	<b>Development and assessment models</b>	<b>Findings from Phase III trials</b>	<b>Planning for Access: providers, service delivery points, and costs</b>	<b>Panel Discussion</b>
		Chair : N.K. Mehra	Chair : K. Mayer	Chair: J. Sokhey	<b>Planning for Introduction and Access:</b>
		Co-Chair : R.Fichorova	Co-Chair : M. Chirenje	Co-chair :	
		Development of a live topical microbicide for women	Male partner circumcision and HIV seroconversion among participants in the phase III Carraguard™ microbicide trial	Perceptions of health care providers regarding the acceptability of intra vaginal rings as a potential delivery method for microbicides.	Introduction: J. Spieler
		Q. Xu (221) Development of a live rectal microbicide	M.L. Gehret (414) Incidence of sexually transmitted and reproductive tract infections among women enrolled in the phase III carraguard trial in South Africa	S. N. Wakasiaka (203) Early closure of a phase III microbicide clinical trial in south India: implications on trial participants and clinical staff	PRO 2000 S. Mc Cormack A. Profy
		T. Wang (306) An in vitro system for HIV-1 selective transmission using human genital epithelial cells	T. Palanee (432) The effect of 6% cellulose sulfate gel On vaginal HIV transmission, Durban, South Africa	J.S. Hallad (475) Phasing introduction – what is the impact? Examination of potential microbicide introduction strategies in India	Truvada from PREP D. Smith K. MacQueen J. Rooney
		Y. Chu (515) Safety of tenofovir gel in a comprehensive murine model	R. Govinden (521) Impact of behavioral change on the incidence of sexually transmitted infections among high risk women in the cellulose sulphate trial in Durban.	A.M Foss (416) Understanding the impact of trial participation on condom use among women in the MDP 301 clinical trial in the Umkhanyakude district of northern KwaZulu Natal.	Microbicides Access Forum Feedback: Y. Tawfik
		B. Herold (389) Do candidate rectal microbicides also need to protect the anal canal?	E. Raju (553) Monthly omt testing for identification of incident HIV infection in a phase III cellulose sulfate trial in Nigeria	A.M. Mzimela (346) Facilitating microbicide use in South Africa: using women's preferences to design distribution strategies	Concluding Remarks K. Dickson
		R.D. Cranston (459)	V. Halpern (106)	F. Terris-Prestholt (247)	

		<i>Disruption of the epithelial barrier by cellulose sulfate: development of a model to assess microbicide safety</i>	<i>The Impact of male partner clinic visits on retention, gel and condom adherence among women participating in a Microbicide trial: HPTN 035 Lilongwe, Malawi</i>	<i>Impact of the pre-mature closure of the cellulose sulphate trial on enrolled participants in Durban</i>	
		<b>P. Mesquita (415)</b>	<b>I.F. Hoffman (303)</b>	<b>D.L. Mbhele (526)</b>	
		<i>The use of oligonucleotide based microarray data from human cervical and vaginal epithelial cell lines as a model for characterizing the potential local toxicity of candidate microbicides</i>			
		<b>J.P. Nuttall</b>			
<b>15:30 – 16:00</b>	<b>AFTERNOON TEA/COFFEE BREAK</b>				
<b>Rutenberg</b>	<b>Rapporteur Session : Chairs : Gita Ramjee, Nomita Chandhiok, Badri Saxena</b>				
	<b>Track A: Gustavo Doncel</b>				
	<b>Track B: Sanjay Mehendale</b>				
	<b>Track C: Betsy Tolley</b>				
	<b>Track D: Kim Dickson</b>				
<b>16:45 – 17:45</b>	<b>CLOSING CEREMONY, CONVENTION CENTRE, HOTEL ASHOK</b>				
	<b>Chief Guest</b>	Mr. Kapil Sibal - Honourable Union Minister For Science and Technology and Earth Sciences, Govt. of India			
	<b>Guest of Honour</b>	Dr. Peter Piot, Executive Director, UNAIDS			