AT-A-GLANCE

# MONDAY NOV, 5

| TIME | SESSION | |
|---|---|---|
| 7:30am<br>7:45am<br>8:00am<br>8:15am | **Breakfast Buffet**<br>**(7:30 - 8:30am)** | |
| | **Session 1 (8:30 — 10:00am)** | |
| 8:30am | **Meeting Opening** | **Holly Janes, Member, Fred Hutch, on behalf of the organizing committee** |
| 8:45am | **Overview of the Global HIV Epidemic and Framework for Discussion of HIV Prevention Efficacy Trial Design Discussions** | **Glenda Gray, President and CEO, South African Medical Research Council** |
| 9:00am | **Highlighting Community Priorities for HIV Prevention Trials** | **Jeremiah Johnson, HIV Project Director, Treatment Action Group** |
| 9:15am | **Current and Future Challenges in Trial Design for Pre-Exposure Prophylaxis in HIV Prevention** | **Deborah Donnell, Associate Member, Fred Hutch and Principal Investigator of HPTN Statistical Data Management Center** |
| 9:30am | **Issues in Microbicide Prevention Trials** | **Elizabeth Brown Member, Fred Hutch and Principal Investigator of MTN Statistical Data Management Center** |
| 9:45am | **Ongoing Vaccine and Monoclonal Antibody Efficacy Trials in the HVTN and Considerations for Sequel Designs** | **Peter Gilbert, Member, Fred Hutch and Principal Investigator of HVTN Statistical Data Management Center** |
| 10:00am | **The Modern Randomized Clinical Trial: Is it time to sharpen a blunt instrument?** | **Janet Wittes, President of Statistics Collaborative, Inc.** |
| 10:15am | **Coffee/Tea Break**<br>**(10:00 — 10:15am)** | |
| | **Session 2 (10:15am — 12:30pm)** | |
| 10:30am | **Regulatory Perspectives for Streamlining HIV Prevention Trials** | **Jeffrey Murray, Deputy Director of Division of Antiviral Products, Center for Drug Evaluation and Research, FDA** |
| 10:45am | **The Averted Infections Ratio and its Connection to Other Measures of Effect** | **David Dunn, Professor of Medical Statistics, Medical Research Council at University College London** |
| 11:00am | **Alternatives to Non-Inferiority in Trials of Novel PrEP Delivery Methods** | **David Glidden, Professor of Biostatistics, University of California, San Francisco** |
| 11:15am | **Designing and Conducting Trials to Reliably Evaluate HIV Prevention Interventions** | **Thomas Fleming, Professor of Biostatistics, University of Washington, Seattle** |
| 11:30am | **Panel: Design Challenges and Approaches Developing Long-Acting, Drug-Based Prevention Products and Floor Discussion** | **Moderated by: Edward Cox, Director of Office of Antimicrobial Products, FDA** |
| 11:45am | | |
| 12:00pm<br>12:15pm | | |
| 12:30pm<br>12:45pm<br>1:00pm<br>1:15pm | **Lunch Break**<br>**(12:30 — 1:30pm)** | |

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| TIME | SESSION | |
|---|---|---|
| 1:30pm | **Session 3 (1:30 — 3:40pm)** | |
| 1:45pm | Tomorrow's HIV Prevention Trials Overview of the Global HIV Epidemic and Framework | Dean Follmann, Chief of Biostatistics Research Branch, National Institute of Allergy and Infectious Diseases |
| 2:00pm | | |
| 2:15pm | | |
| 2:30pm | Panel: Design Challenges and Approaches for Developing Vaccines and Monoclonal Antibodies and Floor Discussion | Moderated by: Dale Hu, Chief of Vaccine Clinical Research Branch, NIAID |
| 2:45pm | | |
| 3:00pm | Panel: Design Challenges and Approaches for Developing On-Demand Products and Floor Discussion | Moderated by: Linda-Gail Bekker, Deputy Director, Desmond Tutu HIV Centre |
| 3:15pm | | |
| 3:30pm | | |
| 3:45pm | Coffee/Tea Break (3:40 — 3:55pm) | |
| | **Session 4 (3:55 — 5:45pm)** | |
| 4:00pm | Pragmatic Trials to Bridge Efficacy to Effectiveness | Laura Balzer, Assistant Professor of Biostatistics, University of Massachusetts, Amherst |
| 4:15pm | | |
| 4:30pm | Lessons for Future Prevention Research from TasP Cluster Randomized Trials | Victor DeGruttola, Professor of Biostatistics, Harvard University |
| 4:45pm | | |
| 5:00pm | Panel: Priorities for future research, data collection, and funding mechanisms and Floor Discussion | Moderated by: Peggy Johnston, Independent Consultant, Vancouver BC |
| 5:15pm | | |
| 5:30pm | Closing Remarks | Organizers |
| 5:45pm | | |
| 6:00pm | | |
| 6:15pm | | |
| 6:30pm | Symposium Closing Reception (6:30 — 8:30pm) | |
| 7:00pm | | |
| 7:30pm | | |
| 8:00pm | | |
| 8:30pm | | |