The HIV prevention landscape is evolving rapidly, and the results of several ongoing HIV prevention efficacy trials — including trials of oral and injectable antiretrovirals, passively infused monoclonal antibodies, and HIV vaccines — will have major implications for the design and conduct of the next generation of trials. This symposium will explore approaches to the statistical design of future randomized trials investigating new behavioral and biomedical HIV intervention strategies — conducted in multiple geographic regions and at-risk populations.

The symposium will feature a series of talks given by biostatistical experts, as well as panel discussions involving clinicians, ethicists, regulators, community members, and sponsors. A series of articles, based on the talks given at the symposium, will be published in Statistical Communications in Infectious Diseases.

Academics working in HIV prevention research; sponsor representatives (BMGF, NIAID); IAVI and IAS/Vaccine Enterprise representatives; representatives of regulatory bodies (FDA, South Africa MRC); PATH; community representatives; product development representatives.
MEETING VENUE
Grand Hyatt Seattle
721 Pine Street
Seattle, WA 98101
Phone: 206.774.1234
www.grandseattle.hyatt.com

MEETING REGISTRATION DESK
The HVTN registration desk will be located in the Princessa Foyer adjacent to the Portland A meeting room

REGISTRATION HOURS
Monday, Nov 5th 7:00am – 7:30pm

NAME BADGES
All registered attendees will be issued a name badge when they check in. Name badges are required for all meeting attendees. Please be sure to wear your name badge at all times when attending meeting-related functions. If you do not have a name badge, or you have lost yours, please return to the registration desk and another badge will be issued.

SPEAKER CHECK-IN
All presenting speakers must check in at the registration desk at least 30 minutes prior to their talk to hand in their presentation slides, unless they have already done so. The AV technician will be available:

AV TECHNICIAN HOURS
Monday, Nov 5th 7:00am – 4:00pm

SYMPOSIUM CLOSING RECEPTION
Please join your colleagues in the Leonesa & Princessa Foyers for a closing reception with dinner, and drinks.

SYMPOSIUM CLOSING RECEPTION
Monday, Nov 5th 6:30 – 8:30pm
Leonesa & Princessa Foyers

PROGRAM-AT-A-GLANCE
For an overview of the meeting program, please refer to the Program-At-A-Glance on pages 12 – 13. The sessions are color coded to indicate talks and meals.

INTERPRETATION SERVICES
There will be no interpretation services at this meeting.

INTERNET ACCESS
Wireless internet service is available for all meeting attendees.

Wi-Fi LOGIN INFORMATION
SSID: Hyatt Meetings
Password: HIVVAX2018

SUBMITTING QUESTIONS
Attendees may submit questions for speakers and panelists electronically, using any device, at this url:
https://www.ustream.tv/qna/20690759

LIVE-STREAMING
For those of you who cannot attend the HIV Prevention Efficacy Trial Designs of the Future Symposium this year, we will be streaming the General Sessions LIVE. If you miss the live feed, the plenaries that have already concluded with also be available. You will be able to access the streaming plenaries by visiting:
http://www.ustream.tv/hIPB0HvqKY
Video Password: #DESIGNS2018

Please note, the slides presented will be linked from the symposium website following the conclusion of the meeting:
Laura Balzer, PhD
Assistant Professor of Biostatistics, University of Massachusetts, Amherst

Laura B. Balzer, PhD MPH, is Assistant Professor of Biostatistics at the University of Massachusetts-Amherst. She earned her PhD from the University of California-Berkeley and completed her post-doctoral studies at the Harvard T.H. Chan School of Public Health. Her areas of expertise include causal inference, machine learning, and dependent data. Dr. Balzer is the Primary Statistician for two cluster randomized trials: the SEARCH study for HIV prevention and treatment in East Africa and the SPIRIT study for TB prevention in Uganda. Her work is supported by the National Institutes of Health (NIH). Dr. Balzer received the ASA’s Causality in Statistics Education Award and the Gertrude M. Cox Scholarship.

Elizabeth Brown, ScD
Member, Fred Hutch and Principal Investigator of MTN Statistical Data Management Center

Dr. Brown is Principal Investigator of the SDMC for the Microbicide Trials Network (MTN), a role she took on in 2011. She is Research Professor of Biostatistics at the University of Washington and Member in the Vaccine and Infectious Disease Division at the Fred Hutchinson Cancer Research Center. Dr. Brown has worked on the statistical design and analysis of HIV/AIDS clinical trials since 2002. Her focus includes the design and analyses of clinical trials for HIV prevention, joint models for longitudinal and survival data, and statistical models for STI transmission. Dr. Brown has been the lead statistician on several HIV prevention trials, including two Phase 3 trials for prevention of mother to child transmission of HIV. Recently, she was the lead statistician on the Phase 3 MTN-020/ASPIRE trial which demonstrated the effectiveness of the dapivirine vaginal ring for HIV prevention. She is currently lead statistician for MTN-025/HOPE, the open label extension study for ASPIRE.

Deborah Donnell, PhD
Associate Member, Fred Hutch and Principal Investigator of HPTN Statistical Data Management Center

As the Principal Investigator of the Statistical and Data Management Center (SDMC) for the HPTN, Dr. Donnell oversees statistical design and analysis as well as data management operations of the Statistical Center for HIV/AIDS Research and Prevention. She is Associate Member in the Vaccine and Infectious Disease Division at the Fred Hutchinson Cancer Research Center and Affiliate Associate Professor in the Department of Global Health at the University of Washington. Dr. Donnell has been engaged in HIV prevention research since 1993, and has extensive management and scientific expertise. Her research interests include the conduct, design, and monitoring of randomized clinical trials; the analysis of complex behavioral and adherence data with application to efficacy and effectiveness; and use and applications of surveillance data to HIV prevention research. She has been lead protocol statistician on six Phase III HIV prevention trials, both domestic and international, including the Partners PrEP trial that supported FDA approval of TDF/FTC. She is the author or coauthor of more than 200 publications and a member of the American Statistical Association and the Society for Clinical Trials.

David Dunn, PhD
Professor of Medical Statistics, Medical Research Council at University College London

David Dunn is a Professor of Medical Statistics at the UK MRC Clinical Trials Unit, University College London. He joined the Unit in 1998 after previous spells at the London School of Hygiene and Tropical Medicine and the Institute of Child Health, where he worked on the epidemiology of several infectious diseases. In 1997 he gained a PhD on statistical issues in the vertical transmission of HIV infection, stemming from his work on the European Collaborative Study. His main current research interests are HIV prevention, HIV drug resistance, the collection/analysis of safety data, and non-inferiority RCTs. He collaborated with Professor Sheena McCormack on the PROUD trial, a pragmatic RCT to assess the effectiveness of pre-exposure prophylaxis (PrEP) to reduce the risk of HIV transmission among gay men in the UK. Following on from PROUD, Dr. Dunn has been exchanging ideas with Professor Dave Glidden (UCSF) on challenges in the design of future PrEP trials. He is also closely involved in the international PrEPVacc trial, which will simultaneously evaluate two experimental combination vaccine regimens versus placebo as well as two different PrEP regimens.

Thomas Fleming, PhD
Professor of Biostatistics, University of Washington, Seattle

Dr. Thomas Fleming is a professor and former department chair of the University of Washington Department of Biostatistics. He is also a member of the Fred Hutchinson Cancer Research Center, and the former Director of the Statistical Center for HIV/AIDS Prevention Trial Network, NIAID. Dr. Fleming has authored or coauthored several books and more than 250 research articles in peer-reviewed journals, many regarding the development of state-of-the-art methods for the design, conduct and analysis of clinical trials. His landmark research on the prevention of transmission of HIV appeared in NEJM in 2011. This research, on which he was senior author, was recognized by Science Magazine as the scientific “Breakthrough of the Year”. He has chaired or served on Data Monitoring Committees for more than 200 clinical trials. He currently serves as a Special Government Employee for the FDA, and for more than 25 years, has been a regular member of several FDA Advisory Committee. He’s been invited to serve as a voting member on more than 100 occasions. Over the course of his career, Dr. Fleming has received numerous awards, including the FDA Commissioner’s Special Citation Award for Extraordinary Contribution to the Agency. In 2012, he was elected to membership in the Institute of Medicine of the National Academies, and in 2015, to membership in the National Academy of Medicine.
Dean Follmann, PhD
Chief of Biostatistics Research Branch, NIAID

Dr. Follmann is Chief of the Biostatistics Research Branch at the National Institute of Allergy and Infectious Diseases (NIAID), a role he has held for the past 16 years. He has authored or co-authored more than 250 peer-reviewed research articles and received numerous awards, including the NIH Director’s Award in 2010 and Fellow of the American Statistical Association in 2003. He leads a group of biostatistical faculty involved in overseeing large multi-center studies, including those conducted by the three large HIV prevention networks. His pioneering work in biostatistical methods for HIV prevention includes the development of baseline immunogenicity predictor and closeout placebo vaccination methods for evaluating immune response biomarkers as surrogates of protection; chop-lump tests for analyzing mixed binary-continuous data such as HIV viral load; and multiple outpatuation, a method for analyzing complex clustered data. He serves on numerous committees and advisory boards at the US Food and Drug Administration, at the National Institutes of Health, and on committees guiding consortium research in infectious diseases.

David Glidden, PhD
Professor of Biostatistics, University of California, San Francisco

Dr. Glidden is Professor of Biostatistics at the University of California, San Francisco. His work focuses on the prevention and treatment of HIV infection. He has been involved in studies of HIV prevention for over 12 years. He was the statistician for the iPrEx trial — the first trial to report the efficacy of oral PrEP — and worked on the drug’s approval by the FDA. Dr. Glidden’s current work involves studies of the global scale-up of PrEP, innovative designs and statistical analyses of new PrEP agents, and pharmacologic markers of PrEP exposure. He also collaborates on studies of the outcomes of HIV treatment in resource-limited settings. In these settings many patients are absent from clinics, and statistical issues such as clustering, competing risk/multiple outcomes, time-dependent covariates and informative censoring must be handled. Alongside his colleagues he has pioneered sampling-based approaches to losses to follow-up which have given rigorous information about treatment outcomes. He also collaborates for groups in neurology, pediatrics, LGBT health and nephrology and teaches in his department’s MCR and Ph.D. programs.

Glenda Gray, MD
President and CEO, South African Medical Research Council

Dr. Gray is the President and CEO of the South African Medical Research Council. She is a Research Professor of Paediatrics at the University of the Witwatersrand, and a director at the Perinatal HIV Research Unit in Soweto. Trained as a paediatrician, she was awarded a Fogarty Training Fellowship at Columbia University in 1999 and also completed an intensive program on clinical epidemiology at Cornell University. Based in South Africa, she is the Co-PI of the HVTN and Director of HVTN Africa Programs. She has expertise in the field of mother to child transmission of HIV, adolescent HIV prevention and treatment, and HIV vaccine and microbicide research. She led the first clinical trials involving HIV vaccines in the Republic of South Africa. She was the Protocol Chair for the first phase 2B HIV vaccine trial to be conducted in sub-Saharan Africa, and was in charge of the early clinical development of South Africa’s first two candidate DNA and MVA HIV vaccines. She was the International Vice Chair for Vaccines for the NIH-funded IMPAACT network until 2010. She has received numerous awards and accolades, including the 2002 Nelson Mandela Health and Human Rights Award for pioneering work done in the field of Mother-to-Child Transmission of HIV, together with James McIntyre, and in 2012, the Order of Mapungubwe, South Africa’s highest honor, for achievements in the international arena which have served South Africa’s interests. She is a member of the Academy of Science in South Africa, and Chair of their Standing Committee on Health; and was elected foreign associate into the US Institute of Medicine of the National Academy of Sciences. She has serves on a large number of expert panels and advisory boards.
ABOUT

SPEAKER BIOS

Victor De Gruttola, ScD
Professor of Biostatistics, Harvard University

Dr. De Gruttola is Research Professor of Biostatistics at Harvard University. He served as Director of the Statistical Coordinating Center for the adult project of the AIDS Clinical Trials Group (ACTG) from 1996-2003 and as Biostatistics Department Chair from 2009-2015. His research activities focus on developing statistical methods required for appropriate public health response to the AIDS epidemic. The aspects of the epidemic on which he has worked include transmission of the Human Immunodeficiency Virus (HIV), natural history of infection with HIV, and clinical research on AIDS therapies; most recently his research focus has been on HIV prevention. His research focus includes not only development of statistical methodology, but also public health surveillance systems, medical issues surrounding HIV infection, and concerns of communities most affected by the epidemic. The goals include forecasting future AIDS incidence, developing strategies for clinical research on HIV infection, and evaluating the public health impact of antiviral treatment. The statistical issues on which Dr. De Gruttola has been engaged include evaluating the degree to which the treatment response of markers of HIV infection constitute adequate evidence for clinical efficacy. He has also worked on projections of AIDS incidence using data from the New York City Health Department. A recent focus has been the statistical design of the Botswana Combination Prevention Project (BCPP), a trial investigating the impact of a combination prevention package on HIV incidence in 30 communities, using a pair-matched, cluster-randomized trial design.

Jeremiah Johnson, MPH
HIV Project Director, Treatment Action Group

Mr. Johnson is the HIV Project Director for the Treatment Action Group (TAG). Like so many working in the field of HIV/AIDS, Jeremiah’s career in HIV/AIDS advocacy has grown from his personal experiences with the virus. Jeremiah was 25 when he was diagnosed with HIV—part of a young gay male demographic that is especially vulnerable to HIV infection in the United States. Serving as a Peace Corps volunteer at the time, Jeremiah immediately found himself dealing with discrimination when the Peace Corps decided to dismiss him from service based solely on his HIV status. He took action, and with the help of the ACLU he soon had the Peace Corps’s policy overturned. The experience fueled his passion for advocacy and, ever since, he has been determined to combat other laws and policies that discriminate against people living with HIV/AIDS or those who are most at risk for it. Prior to joining TAG in 2013, Mr. Johnson worked in Peru with an AIDS service organization, in rural Colorado as a case manager and prevention specialist, and interned with the United Nations Programme on HIV/AIDS. He holds an MPH from Columbia University. As part of TAG, he works to promote better HIV surveillance methods, effective utilization of existing and future research, and prevention strategies that take into account the true complexity of HIV in the United States. Mr. Johnson was honored by POZ magazine as one of the top 100 HIV/AIDS activists in the United States in 2010.
Jeffrey Murray, MD  
Deputy Director of Division of Antiviral Products, Center for Drug Evaluation and Research, FDA  
Jeffrey S. Murray, MD, MPH, is Deputy Director of the Division of Antiviral Products (DAVP) at the US Food and Drug Administration. He has worked in the Division in various capacities for over 25 years. At DAVP, Dr. Murray has reviewed and approved marketing applications for drugs to treat and/or prevent HIV, influenza, herpes viruses, hepatitis B and C. He has co-authored publications and FDA guidance documents for HIV drug development, HIV fixed dose combinations for the President’s Emergency Plan for AIDS Relief (PEPFAR) and the development of drugs for the treatment of Influenza and Chronic Hepatitis C. Dr. Murray received his MD from The Ohio State University and his MPH in Epidemiology and Biostatistics from George Washington University in Washington, DC. He completed his internship, residency and chief residency in Internal Medicine at Riverside Methodist Hospitals in Columbus, followed by a fellowship in Infectious Diseases at the University of Cincinnati Medical Center. Dr. Murray is board certified in Internal Medicine and Infectious Diseases.

Janet Wittes, PhD  
President of Statistics Collaborative, Inc.  
Janet Wittes, PhD is President of Statistics Collaborative, Inc. which she founded in 1990. Previously, she was Chief, Biostatistics Research Branch, National Heart, Lung, & Blood Institute (1983–89). Her 2006 monograph, “Statistical Monitoring of Clinical Trials – A Unified Approach” by Proschan, Lan, and Wittes, deals with sequential trials, including aspects of non-inferiority. Her research has focused on design of randomized clinical trials, capture recapture methods in epidemiology, and sample size recalculation. She has served on a variety of advisory committees and data monitoring committees for government (NHLBI, the VA, NEI, and NCI) and industry. For the FDA, she has been a regular member of the Circulatory Devices Advisory Panel and has served as an ad hoc member of several other panels. Currently, she is a regular member of the Gene Therapy Advisory Committee. She was formerly Editor in Chief of Controlled Clinical Trials (1994–98).
Regulatory Perspectives for Streamlining HIV Prevention Trials
10:15 – 10:35am
Jeffrey Murray, MD, Deputy Director of Division of Antiviral Products, Center for Drug Evaluation and Research, FDA

The Averted Infections Ratio and its Connection to Other Measures of Effect
10:35 – 10:55am
David Dunn, PhD, Professor of Medical Statistics, Medical Research Council at University College London

Alternatives to Non-Inferiority in Trials of Novel PrEP Delivery Methods
10:55 – 11:15am
David Glidden, PhD, Professor of Biostatistics, University of California, San Francisco

Designing and Conducting Trials to Reliably Evaluate HIV Prevention Interventions
11:15 – 11:35am
Thomas Fleming, PhD, Professor of Biostatistics, University of Washington, Seattle

Panel: Design Challenges and Approaches For Developing Long-Acting, Drug-Based Prevention Products and Floor Discussion
11:35am – 12:30pm
Moderated by: Lut Van Damme, PhD, Senior Program Officer, Bill and Melinda Gates Foundation
SESSION 3 1:30 – 3:40pm

1:30 – 3:40pm  Leonesa Ballrooms

Tomorrow’s HIV Prevention Trials Overview of the Global HIV Epidemic and Framework
1:30 – 1:50pm
Dean Follmann, PhD,
Chief of Biostatistics Research Branch, National Institute of Allergy and Infectious Diseases

Panel: Design Challenges and Approaches for Developing Vaccines and Monoclonal Antibodies and Floor Discussion
1:50 – 2:45pm
Moderated by: Dale Hu, MD,
Chief of Vaccine Clinical Research Branch, NIAID

Panel: Design Challenges and Approaches for Developing On-Demand Products and Floor Discussion
2:45 – 3:40pm
Moderated by: Linda-Gail Bekker, MD,
Deputy Director, Desmond Tutu HIV Centre

COFFEE/TEA BREAK 3:40 – 3:55pm

3:40 – 3:55pm  Leonesa Foyer

SESSION 4 3:55 – 5:45pm

3:55 – 5:45pm  Leonesa Ballrooms

Pragmatic Trials to Bridge Efficacy to Effectiveness
3:55 – 4:15pm
Laura Balzer, PhD,
Assistant Professor of Biostatistics,
University of Massachusetts, Amherst

Lessons for Future Prevention Research from TasP Cluster Randomized Trials
4:15 – 4:35pm
Victor De Gruttola, ScD,
Professor of Biostatistics, Harvard University

Panel: Priorities for Future Research, Data Collection, and Funding Mechanisms and Floor Discussion
4:35 – 5:30pm
Moderated by: Peggy Johnston, PhD
Consultant, IAS/Global HIV Vaccine Enterprise

Closing Remarks
5:30 – 5:45pm
Organizers
Panel: Design Challenges and Approaches for Developing Long-Acting, Drug-Based Prevention Products

Moderator: Lut Van Damme, PhD
Senior Program Officer, Bill and Melinda Gates Foundation

Panelists: Edward Cox, MD
Director of Office of Antimicrobial Products, FDA
Jeremy Sugarman, MD
Professor of Bioethics and Medicine, Johns Hopkins University
Danielle Wenner, PhD
Assistant Professor of Philosophy, Carnegie Mellon University
Patricia Segura, RN, MPH
Head of the HIV/STI and Hepatitis National Program, Peruvian Ministry of Health
Ernest Hopkins, BA
Director of Legislative Affairs, San Francisco AIDS Foundation
Jim Rooney, MD
Vice President of Medical Affairs, Gilead Sciences

Panel: Design Challenges and Approaches for Developing Vaccines and Monoclonal Antibodies

Moderator: Dale Hu, MD
Chief of Vaccine Clinical Research Branch, NIAID

Panelists: Carol Weiss, MD, PhD
Laboratory Chief and Principal Investigator, Office of Vaccines Research and Review, FDA
Merlin Robb, MD
Program Director for US Military HIV Research Program
Lucio Gama, PhD
Director of Scientific Collaborations, Vaccine Research Center, NIAID
Ames Dhai, PhD
Director of Steve Biko Centre for Bioethics, Wits University
Mark Hubbard
Education Liaison, Tennessee Association of People With AIDS
Joshua Chen, PhD
Global Head of Biostatistics and Programming, Sanofi Pasteur

Panel: Design Challenges and Approaches for Developing On-Demand Products

Moderator: Linda-Gail Bekker, MD
Deputy Director, Desmond Tutu HIV Centre

Panelists: Charu Mullick, MD
Medical Officer, Division of Antiviral Products, FDA
Liza Dawson, PhD
Research Ethics Team Leader, Division of AIDS, NIAID
Morenike Giwa Onaiwu, MAED
Chair, Global Community Advisory Board, AIDS Clinical Trials Group
Jim Pickett, BA
Senior Director of Prevention Advocacy and Gay Men’s Health, AIDS Foundation of Chicago
Jill Schwartz, MD
Medical Director, CONRAD

Panel: Priorities for Future Research, Data Collection, and Funding Mechanisms

Moderator: Peggy Johnston, PhD
Consultant, IAS/Global HIV Vaccine Enterprise

Panelists: Sheryl Zwerski, RN
Director of Prevention Sciences Program, NIAID
Mary Marovich, MD
Director of Vaccine Research Program, NIAID
Nina Russell, MD
Deputy Director, HIV, Bill and Melinda Gates Foundation
Charles Gombar, PhD
Deputy Director, Strategy and Product Development, HIV, Bill and Melinda Gates Foundation
### MONDAY NOV, 5

#### AT-A-GLANCE

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<tr>
<th>TIME</th>
<th>SESSION</th>
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<tr>
<td>7:00am</td>
<td>Breakfast Buffet</td>
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<td>7:30am</td>
<td>(7:00 - 8:30am)</td>
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<tr>
<td>8:30am</td>
<td>Meeting Opening</td>
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<tr>
<td>8:45am</td>
<td>Overview of the Global HIV Epidemic and Framework for Discussion of HIV Prevention Efficacy Trial Design Discussions</td>
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<tr>
<td>9:00am</td>
<td>Highlighting Community Priorities for HIV Prevention Trials</td>
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<td>9:15am</td>
<td>Current and Future Challenges in Trial Design for Pre-Exposure Prophylaxis in HIV Prevention</td>
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<td>9:30am</td>
<td>Issues in Microbicide Prevention Trials</td>
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<td>9:45am</td>
<td>Ongoing Vaccine and Monoclonal Antibody Efficacy Trials in the HVTN and Considerations for Sequel Designs</td>
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<td>10:00am</td>
<td>The Modern Randomized Clinical Trial: Is It Time to Sharpen a Blunt Instrument?</td>
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<td>10:15am</td>
<td>Coffee/Tea Break</td>
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<td>10:30am</td>
<td>Regulatory Perspectives for Streamlining HIV Prevention Trials</td>
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<td>Designing and Conducting Trials to Reliably Evaluate HIV Prevention Interventions</td>
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<td>12:00pm</td>
<td>Panel: Design Challenges and Approaches For Developing Long-Acting, Drug-Based Prevention Products and Floor Discussion</td>
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<td>12:30pm</td>
<td>Lunch Break</td>
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#### Session 1 (8:30 — 10:00am)

- Meeting Opening: Holly Janes, PhD Member, Fred Hutch, on behalf of the organizing committee
- Overview of the Global HIV Epidemic and Framework for Discussion of HIV Prevention Efficacy Trial Design Discussions: Glenda Gray, MD, President and CEO, South African Medical Research Council
- Highlighting Community Priorities for HIV Prevention Trials: Jeremiah Johnson, MPH, HIV Project Director, Treatment Action Group
- Current and Future Challenges in Trial Design for Pre-Exposure Prophylaxis in HIV Prevention: Deborah Donnell, PhD, Associate Member, Fred Hutch and Principal Investigator of HPTN Statistical Data Management Center
- Issues in Microbicide Prevention Trials: Elizabeth Brown, ScD, Member, Fred Hutch and Principal Investigator of MTN Statistical Data Management Center
- Ongoing Vaccine and Monoclonal Antibody Efficacy Trials in the HVTN and Considerations for Sequel Designs: Peter Gilbert, PhD, Member, Fred Hutch and Principal Investigator of HVTN Statistical Data Management Center
- The Modern Randomized Clinical Trial: Is It Time to Sharpen a Blunt Instrument?: Janet Wittes, PhD, President of Statistics Collaborative, Inc.

#### Session 2 (10:15am — 12:30pm)

- Regulatory Perspectives for Streamlining HIV Prevention Trials: Jeffrey Murray, MD, Deputy Director of Division of Antiviral Products, Center for Drug Evaluation and Research, FDA
- The Averted Infections Ratio and Its Connection to Other Measures of Effect: David Dunn, PhD, Professor of Medical Statistics, Medical Research Council at University College London
- Alternatives to Non-Inferiority in Trials of Novel PrEP Delivery Methods: David Glidden, PhD, Professor of Biostatistics, University of California, San Francisco
- Designing and Conducting Trials to Reliably Evaluate HIV Prevention Interventions: Thomas Fleming, PhD, Professor of Biostatistics, University of Washington, Seattle
- Panel: Design Challenges and Approaches For Developing Long-Acting, Drug-Based Prevention Products and Floor Discussion: Moderated by: Lut Van Damme, PhD, Senior Program Officer, Bill and Melinda Gates Foundation

### HIV Prevention Efficacy Trial Designs of the Future 2018
<table>
<thead>
<tr>
<th>TIME</th>
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<tr>
<td>1:30pm</td>
<td>Session 3 (1:30 — 3:40pm)</td>
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| 1:45pm | Tomorrow’s HIV Prevention Trials Overview of the Global HIV Epidemic and Framework  
Dean Follmann, PhD, Chief of Biostatistics Research Branch, National Institute of Allergy and Infectious Diseases |
| 2:00pm | Session 4 (3:55 — 5:45pm) |
| 2:15pm | Panel: Design Challenges and Approaches for Developing Vaccines and Monoclonal Antibodies and Floor Discussion  
Moderated by: Dale Hu, MD, Chief of Vaccine Clinical Research Branch, NIAID |
| 2:30pm | Coffee/Tea Break  
(3:40 — 3:55pm) |
| 2:45pm | Panel: Design Challenges and Approaches for Developing On-Demand Products and Floor Discussion  
Moderated by: Linda-Gail Bekker, MD, Deputy Director, Desmond Tutu HIV Centre |
| 3:00pm | |
| 3:15pm | |
| 3:30pm | |
| 3:45pm | |
| 4:00pm | Pragmatic Trials to Bridge Efficacy to Effectiveness  
Laura Balzer, PhD, Assistant Professor of Biostatistics, University of Massachusetts, Amherst |
| 4:15pm | Lessons for Future Prevention Research from TasP Cluster Randomized Trials  
Victor DeGruttola, ScD, Professor of Biostatistics, Harvard University |
| 4:30pm | Panel: Priorities for Future Research, Data Collection, and Funding Mechanisms and Floor Discussion  
Moderated by: Peggy Johnston, PhD, Consultant, IAS/Global HIV Vaccine Enterprise |
| 4:45pm | Closing Remarks  
Organizers |
| 5:00pm | |
| 5:15pm | |
| 5:30pm | |
| 5:45pm | |
| 6:00pm | |
| 6:15pm | |
| 6:30pm | Symposium Closing Reception  
(6:30 — 8:30pm) |
| 7:00pm | |
| 7:30pm | |
| 8:00pm | |
| 8:30pm | |
The HIV Prevention Efficacy Trial Designs of the Future Symposium will convene throughout the lobby level of the Grand Hyatt. All meeting spaces can be accessed through the Princessa Foyer. If you need additional assistance, an attendant at the Registration Desk will be happy to assist you.