

Pre-Exposure Prophylaxis Research and Regulatory Issues Planning Meeting
Renaissance Arlington Capital View Hotel
2800 South Potomac Ave
Arlington, VA 22202
June 23, 2016

****DRAFT AGENDA****

| SESSION | Speaker/Panelist |
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| 9:00 AM Welcome and Introductions | Veronica Miller, PhD, Forum for Collaborative HIV Research |
| 9:30 AM Session 1: Setting the Stage-Current Perspectives on PrEP Research | Moderators: Pedro Goicochea, MSc, MA, Forum for Collaborative HIV Research Ben Hauschild, MPH, Forum for Collaborative HIV Research |
| Regulatory Perspectives | Kimberly Struble, PharmD, U.S. Food and Drug Administration |
| Regulatory Perspectives | Filip Josephson, MD, PhD, Swedish Medical Products Agency |
| Clinical and Systems Perspective | Michael Horberg, MD, MAS, FACP, Kaiser Permanente Medical Group |
| Update on WHO Meeting on PrEP | Robert Grant, MD, MPH, UCSF, Gladstone Institute of Virology and Immunology |
| Update on upcoming PrEP Meeting in Europe | Julie Fox, King's College London |
| 10:20 AM Session 2 --Focusing on Clinical Trial Designs | Moderators: Kenneth Mayer, MD, The Fenway Institute; Beth Israel Deaconess Medical Center; Harvard Medical School Veronica Miller, PhD, Forum for Collaborative HIV Research Myron Cohen, MD, University of North Carolina School of Medicine Q&A and discussion (all) |
| 11:10 AM BREAK | |
| 11:40 AM Session 3 --Panel Discussion: What is needed for new PrEP Products? | Moderator: Kenneth Mayer, MD, The Fenway Institute; Beth Israel Deaconess Medical Center; Harvard Medical School Veronica Miller, PhD, Forum for Collaborative HIV Research Ya'ir Aizenman, Mylan, Inc. Nikos Dedes, Positive Voice Lynda Dee, JD, AIDS Action Baltimore, Inc., CARE Collaboratory CAB David Evans, Project Inform Tim Horn, Treatment Action Group |
| 12:30 PM LUNCH | |
| 1:30 PM Session 4 --Planning an open public meeting on guidance for HIV prevention clinical trial designs including new modalities and formulations as well as "cousin" drugs with similar biochemistry | Moderator: Myron Cohen, MD, University of North Carolina School of Medicine Amy Cutrell, ViiV Healthcare Dave Glidden, PhD, University of California, San Francisco Filip Josephson, MD, PhD, Swedish Medical Products Agency Scott McCallister, MD, Gilead Kimberly Struble, PharmD, U.S. Food and Drug Administration |
| 2:15 PM Session 5--Creating an ongoing working group to facilitate the regulatory path for identifying and validating biomarkers for HIV-infection as an endpoint in prevention trials | Moderator: Veronica Miller, PhD, Forum for Collaborative HIV Research Vanessa Elharrar, MD, Office of AIDS Research (tbc) Robert Grant, MD, MPH, UCSF, Gladstone Institute of Virology and Immunology Dagna Laufer, MD, International AIDS Vaccine Initiative Bach-Yen Nguyen, MD, Merck Research Laboratories Mitchell Warren, AIDS Vaccine Advocacy Coalition |
| 2:15 PM BREAK | |
| 2:45 PM Session 6 -- Identifying strategies to address the need for ARV-based prevention for women in the US | Moderator: Adaora Adimora, MD, MPH, University of North Carolina-Chapel Hill Sally Hodder, MD, West Virginia University School of Medicine Mitesh Desai, MD, MPH, Centers for Disease Control and Prevention (tbc) Dazon Dixon Diallo, MPH, DHL, SisterLove Shannon Weber, MSW, University of California, San Francisco |
| 3:30 PM SUMMING UP | |
| 4:00 PM ADJOURN | |