School of Public Health
UNIVERSITY OF CALIFORNIA, BERKELEY

Forum for Collaborative HIV Research

Regulatory Pathway for HIV Cure Research: Developing Consensus, Part 1
June 17, 2014
Kaiser Family Foundation, Barbara Jordan Conference Center
1330 G Street NW, Washington, DC

8:30	Welcome and Meeting Goals	Veronica Miller (Forum) and Dan Kuritzkes (HMS/BWH)
8:40	Facilitating Translational Research and the Co-evolution of Research and Regulatory Strategies - Stakeholder Perspectives	Karen Midthun (CBER/FDA) – Opening remarks Moderated by Veronica Miller (Forum) and Dan Kuritzkes (HMS/BWH) • Debra Birnkrant (CDER/FDA) • Daria Hazuda (Merck) • Mark Harrington (TAG) • Sarah Read (DAIDS/NIH) • Paul Sato (OAR/NIH)
9:10	Arriving at a Common Language: Clarity of Definitions, Expectations and Goals • Defining "Cure" • Role of Animal Models in Pre-Clinical Research • Biomarkers and Analytic Treatment Interruptions	Moderated by John Mellors (UPitt) and Mike Miller (Merck) • Damon Deming (CDER/FDA) • Susan Fiscus (UNC), presenter • Joe Fitzgibbon (DAIDS/NIH), presenter • Richard Jefferys (TAG) • Rowena Johnston (amfAR), presenter
10:10	Break	
10:30	Ethics and Fairness in Trial Recruitment, Participant Education and Informed Consent: • Informed Consent for HIV Cure Trials • Patient Perceptions of Risk and Decision Making Process	Presented and moderated by David Evans (PI) and Tim Henrich (HMS/BWH) • Nikos Dedes (EMA Managing Board) • George Hanna (BMS) • Gail Henderson (UNC) • Richard Klein (OTC/FDA) • Jeremy Sugarman (JHMI)
11:30	Cure Research in Maternal/Pediatric Setting	Presented by Deborah Persaud (JHMI) and P1115 Protocol Team Moderated by Sandra Nusinoff Lehrman (Forum Industry co-chair, Merck) • Yvonne Bryson (UCLA, P1115) • Ellen Chadwick (Northwestern, P1115) • Mark Cotton (UStellenbosch, P1115)

1608 Rhode Island Avenue NW • Suite 212 • Washington DC 20036
202.833.4617 • Fax: 202.872.4316
www.hivforum.org

		• Linda Lewis (CDER/FDA) • Boris Renjifo (AbbVie) • Seema Shah (DAIDS/NIH)
12:30	Lunch	
13:10	Managing Risk Benefit in Clinical Trials: • Common and Unique Issues Across HIV Cure Interventions • Analytical Treatment Interruptions • Risk Mitigation Strategies	Presented and moderated by Joe Eron (UNC) and Jintanat Ananworanich (MHRP) • Lynda Dee (AAB) • Ron Mitsuyasu (UCLA) • Rob Murphy (Northwestern) • Adam Sherwat (CDER/FDA) • Neil Shortman (ViiV)
13:55	Case Study: Kick and Kill - REDUC Trial	Presented by Lars Østergaard (Aarhus) Moderated by Janet Siliciano (JHMI) • Giulio Maria Corbelli (EATG) • Romas Geleziunas (Gilead) • Gail Henderson (UNC) • Filip Josephson (SMPA) • Kim Struble (CDER/FDA)
14:40	Case Study: VRCO1 and Analytical Treatment Interruption in Early/Acutely-infected Patients - RV397 Protocol	Presented by Jintanat Ananworanich (MHRP) Moderated by Pablo Tebas (UPenn) • Steve Deeks (UCSF) • Nicole Frahm (HVTN/UW) • Filip Josephson (SMPA) • Jeff Taylor (UNC CAB) • Carol Weiss (CBER/FDA) • Brian Woodfall (Janssen)
15:25	Break	
15:45	Hypothetical Case Study: Combination Protocol –vorinostat and CAR-modified CD8+ T cells	Combination Therapy Guidance presented by Jeff Murray (CDER/FDA) Moderated by Sharon Lewin (Monash) • Yuman Fong (RAC, COH) • Ilan Irony (CBER/FDA) • David Margolis (UNC) • Matt Sharp (CAB) • Geoff Symonds (CALimmune)
16:30	Closing Remarks and Meeting Discussion	David Margolis (UNC) and Veronica Miller (Forum)

This project is funded by the Collaboratory of AIDS Researchers for Eradication (CARE), NIAID/NIMH U19 AI096113

Additional project support provided by: