



# PrEP Regulatory and Research Issues Planning Meeting

**June 23, 2016**  
**Arlington, VA**



*Facilitating collaborative research in drug  
development and health policy*

# The Forum for Collaborative HIV Research

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Established in 1997, the Forum, is a public/private partnership addressing cutting edge science and policy issues through a process of stakeholder engagement and deliberation



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# Forum Staff

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# Special Thanks

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- Kimberly Struble
- Filip Josephson
- Robert Grant
- Myron Cohen
- Ken Mayer



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# Forum PrEP Project

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- PrEP Clinical Trialists Working Group
  - Ongoing working group meetings, 2008-2012
- Safety Considerations in the Prevention of Transmission of HIV by Pre-Exposure Prophylaxis
  - Open Meeting, August 2011
- Future of PrEP and Microbicide Research: Trial Design and Regulatory Issues
  - Public Meeting, January 2013



# Pre-Exposure Prophylaxis (PrEP) Regulatory Path Project

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The PrEP Regulatory Path Project aims to address the following questions:

- What is the regulatory path for:
  - new combinations of drugs for ARV-based prevention?
  - new regimens of drugs for ARV-based prevention?
  - new modalities such as long acting injectables for ARV-based prevention?
- What will be the most efficient or cost-effective trial designs for future prevention trials?
- What steps would be necessary so that biomarkers could be used as surrogates for HIV infection in prevention studies?
- What research needs to be done to better inform ARV-based prevention for populations not included in clinical research?



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# Today's Agenda

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- Session 1: Setting the Stage-Current Perspectives on PrEP Research
- Session 2 --Focusing on Clinical Trial Designs
- Session 3 --Panel Discussion: What is needed for new PrEP Products?
- 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
- 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
- Session 6 -- Identifying strategies to address the need for ARV-based prevention for women in the US