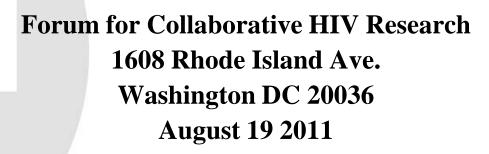


Located in Washington DC, part of the School of Public Health





# SAFETY ISSUES IN PREP PROPOSALS FOR MANAGEMENT OF SAFETY CONCERNS IN SCALE-UP





# ACKNOWLEDGMENTS

- PrEP Trialists Working Group
- Panelist, Moderators and Presenters
- Kimberly Struble & Kendall Marcus, FDA
- Forum staff
  - Jur Strobos
  - Ben Hauschild
- Logistics support by Meetings By Design
- UCDC AV team



## FORUM MISSION & FUNCTION

- To enhance and facilitate HIV research
  - Identify gaps
  - Bring together experts from all stakeholder groups
  - Review, discuss, recommend
- Catalyze stakeholders to act on the recommendations



## FORUM EC MEMBERSHIP

- Academia
- Advocacy/community groups
- Foundations
  - BM Gates Foundation, Clinton Foundation, amfAR, EGPAF
- Governmental agencies
  - US HHS (CDC, FDA, HRSA, NIH), State (OGAC, USAID)
  - EMEA
  - ANRS
  - Public Health Agency of Canada
- World Bank
- Industry
  - 22 pharmaceutical, diagnostic companies
- Health Care Insurers



#### PREP: A NEW "FIRST" IN HIV/AIDS

- An open public meeting convened to address safety and public health concerns associated with the potential approval of ARVs for prevention
- An opportunity for experts from each sector to present PrEP issues from their perspectives
- Joint discussion by all stakeholders
- An opportunity for regulators and other public health leaders to obtain input from all stakeholders



# MEETING OBJECTIVES

- To identify safety issues associated with the introduction of PrEP
- To discuss potential remedies to mitigate any safety concerns
- To discuss the public health implications of PrEP scale-up
- To disseminate the discussion to the broadest possible audience



#### FORUM METHODOLOGY - 1

- Background research
- Stakeholder interviews
  - FDA; EMA
  - NIH
  - Public Health Agencies
    - CDC; State and Local
  - PrEP Trialists
  - Community Advocates
  - HIV Medicine Providers
  - Insurers



#### FORUM METHODOLOGY - 2

- Agenda
  - Consultative process
  - Inclusive
- Process: dialogue between expert stakeholder representatives
  - Everyone brings their expertise to the table
  - Formal presentations limited to background and/or overview topics



#### **TODAY'S EVENT**

- As of Thursday August 18:
  - 141 on-site participants
  - 70 web-cast participants
- Meeting is being webcast live via cameras in the meeting room
- Audience (live and on-line) participation:
  - Please submit your questions in writing (notepaper provided) or on-line
  - Moderators will integrate into panel discussions



# **AGENDA**

8:30 AM	Introductory Presentations
9:10 AM	Session 1: What safety issues of concern with pre-exposure prophylaxis?
10:25 AM	BREAK
10:40 AM	Session 2: Remedies and their pros and cons
12:15 PM	LUNCH
1:45 PM	Session 3: Public Health Implications
3:00 PM	BREAK
3:15 PM	Session 4: Next Steps
4:00 PM	Session 5: Summary and Action Items
4:30 PM	ADJOURN



# **NEXT STEPS**

- Webcast available online at www.hivforum.org
- Report summarizing the consensus of participants.
  - Goal: advancing research on PrEP and promoting effective public policy
  - Disseminate to FDA and constituencies government, industry, patient advocates, healthcare providers, foundations, health insurers and academia
- Future meetings as needed



# THE FORUM TEAM

