Berkeley Public Health

The Forum for Collaborative Research℠ HIV FORUM

The Forum HIV Prevention Trial Design Public Meeting Series

Webinar 1: High-level review of regulatory frameworks and lessons learned to date

Ocotober 14, 11 am-1 pm EST

Webinar

Overview

This first webinar will review the regulatory framework for clinical trial innovation relevant for PrEP. Regulatory experts from the EU and US will provide a high-level overview, and we will get a glimpse of how a normative body, the WHO interacts with regulatory agencies. Then, we will review how far we have come in PrEP research in the context of the regulatory framework and discuss why we need innovation in trial design for this global health need. This will set the stage for the 2nd webinar (Date to be confirmed) in which we will feature additional high-level regulatory overviews, and discuss the potential path forward. The goal of the two information webinars is to bring the audience up to speed and facilitate their engagement in strategic discussions on forging a feasible path forward. Both webinars will be archived for future access.

AGENDA

11:00 AM	Welcome & Housekeeping	*Tamar Tchelidze, MD, MPH, Sr. Policy Fellow. Forum for Collaborative Research, UC Berkeley*
	Introductory remarks	*Veronica Miller, PhD, Executive Director, Forum for Collaborative Research, UC Berkeley*
	Opening remarks	*Ken Mayer, MD, Medical Research Director. The Fenway Institute/Harvard Medical School*
11:10 AM	**Session I: High-level Overview of Regulatory Frameworks & Innovations**	
		Moderator: Veronica Miller
	Regulatory Frameworks - EU Perspective	*Hans-Georg Eichler, MD, MSc, Senior Medical Officer, European Medicines Agency (EMA)*
	WHO and EMA: Dapivirine Ring Case Study	*Rachel Baggaley, MD, Unit Head, Worl Health Organisation (WHO)*
11:30 AM	Moderated discussion with panelists	*Veronica Miller, PhD, Forum for Collaborative Research; Jeffrey Murray, MD, MPH, Deputy director of Division of Antiviral Products, FDA; Community Representatives: Grace Kumwenda, BA, Pakachere Institute of Health & Development Communication (Africa); Gus Cairns,MA the PrEP in Europe Initiative/EATG, (EU); Mitchell Warren, BA, AVAC (US)*
12:00 PM	**Session II: What have we learned thus far**	
		Moderator: Veronica Miller
12:00 PM	Lessons from PrEP trials to date	*Deborah Donnell, PhD, Principal Staff Scientist, the Vaccine and Infectious Disease Division, Fred Hutchinson Cancer Research Center/HPTN*
	When & why will these approaches no longer "work"?	*Charu Mullick, MD, Medical Officer, U.S. Food and Drug Administration (FDA)*
	Moderated Interactive Panel Discussion: Why do we need a new path forward? Continuing unmet medical need	*Sinead Delany-Moretlwe, PhD, Associate Professor and Director of Research, University of the Witwatersrand; Community representatives: Ntando Yola, BA, Desmond Tutu Health Foundation (Africa); Stacey Hannah, MHS, AVAC (US)*
	Q & A	
12:50 PM	Summary and introduction to next webinar	*Veronica Miller, PhD, Forum for Collaborative Research/ UC Berkeley*
1:00 PM	**ADJOURN**	