

The Forum HIV Prevention Trial Design Public Meeting Series
Webinar 2: High-level review of regulatory frameworks and the way forward
Tuesday, November 10, 2020 11 am - 1 pm EST
Webinar

Overview

The 2nd webinar will discuss the potential path forward regarding clinical trial designs. Similar to the 1st webinar, the 2nd webinar will continue to review the regulatory framework for clinical trial innovation relevant for PrEP. Experts from the US and South Africa will provide a high-level overview. The goal of the first 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	<i>Tamar Tchelidze, MD, MPH, Sr. Policy Fellow. Forum for Collaborative Research, UC Berkeley</i>
	Opening remarks	<i>Veronica Miller, PhD, Executive Director, Forum for Collaborative Research, UC Berkeley</i>
11:10 AM	Session I: High-level Overview of Regulatory Frameworks & Global Initiatives	
11:10 AM	Moderator	<i>Ken Mayer, MD, Medical Research Director. The Fenway Institute/Harvard Medical School</i>
11:10 AM	Regulatory Frameworks - Africa Perspective	<i>Boitumelo Semete-Makokotlela, PhD, MS, Chief Executive Officer of SAHPRA.</i>
11:20 AM	WHO Pre-Qualification Program	<i>Regine Lehnert, MD, adviser to WHO prequalification programme</i>
11:35 AM	Session II: Identifying the need for change	
	Moderator	<i>Veronica Miller, Forum for Collaborative Research, UC Berkeley</i>
11:35 AM	Why do we need a new approach?	<i>Mitchell Warren, BA, Executive Director, AVAC</i>
11:45 AM	Why are we talking about an external control (counterfactual) approach; when has this approach been used in the past? What are the regulatory underpinnings?	<i>Jeffrey Murray, MD, MPH. Deputy Director of the Division of Antiviral Products (DAVP), FDA</i>
12:00 PM	What is a counterfactual and how can a counterfactual external control approach be used in HIV prevention research?	<i>Sandra McCoy, PhD, MPH, Associate Professor, Division of Epidemiology and Biostatistics. UC Berkeley</i>
12:15 PM	Moderated discussion with panelists	<i>Community representatives: Lynda Dee, co-founder AIDS Action Baltimore (US), David Haerry, EATG (EU), Definate Nhamo, Pangaea Zimbabwe AIDS Trust, (Africa).</i>
12:40 PM	Q & A	
1:00 PM	ADJOURN	