The Forum HIV Prevention Trial Design Public Meeting Series

Protocol Design Considerations: Analyses for Efficacy

Day 1

April 13, 11 am - 1 pm ET

Webinar

Overview

The two-day webinar on the Protocol Design Considerations: Analyses for Efficacy will discuss the choice of external controls to derive a counterfactual estimate of HIV incidence in the communities where the trials are conducted. It will also examine the role of the active control as an additional benchmark, as well as ethical considerations. The webinar will include experts from all stakeholder groups to contribute to this important conversation.

	AGENDA	
11:00 AM	Welcome & Housekeeping	Tamar Tchelidze, MD, MPH. Forum for Collaborative Research, UC Berkeley
	Opening remarks	Kenneth Mayer, MD. The Fenway Institute. Harvard Medical School. HIV Forum Co-Chair
11:15 AM	**SESSION 1: Presentations**	
	Moderator	Veronica Miller, PhD. Forum for Collaborative Research, UC Berkeley
	How do you build a counterfactual? What are the possibilities for external controls?	Moupali Das, MD, MPH. Gilead Sciences
	Cross-sectional incidence to build an external control (using recency assay)	Neil Parkin, PhD, Data First Consulting, Inc
	Analysis of external controls: primary & secondary analyses	Jeffrey Murray, MD, MPH. U.S. Food and Drug Administration
11:45 AM	**SESSION 2: Breakout Rooms Take Place Simultaneously**	
	BREAKOUT ROOM 1 (MSM & TGW) Topic: Acceptable Thresholds for Efficacy Moderator: Jeffrey Murray, MD, MPH. U.S. Food and Drug Administration Rapporteur: Kimberly Struble, PharmD. U.S. Food and Drug Administration	**BREAKOUT ROOM 3:** **Topic:** Methods for Deriving Counterfactual Estimate (External Controls); Protocol Design: Screening, Inclusion & Exclusion Criteria **Moderator:** Sinead Delany-Moretlwe, MBBCh, PhD, DTM&H. University of the Witwatersrand **Rapporteur:** Amy Cutrell, MS. ViiV Healthcare
	BREAKOUT ROOM 2 (cisgender women) **Topic:** Acceptable Thresholds for Efficacy **Moderator:** Raphael Landovitz, UCLA Center for Clinical AIDS Research & Education **Rapporteur:** Charu Mullick, MD. U.S. Food and Drug Administration	
12:55 PM	**NEXT STEPS**	Veronica Miller, PhD. Forum for Collaborative Research, UC Berkeley
1:00 PM	**ADJOURN**	

The Forum HIV Prevention Trial Design Public Meeting Series

Protocol Design Considerations: Analyses for Efficacy

Day 2

April 14, 11 am - 1 pm ET

Webinar

Overview

The two-day webinar on the Protocol Design Considerations: Analyses for Efficacy will discuss the choice of external controls to derive a counterfactual estimate of HIV incidence in the communities where the trials are conducted. It will also examine the role of the active control as an additional benchmark, as well as ethical considerations. The webinar will include experts from all stakeholder groups to contribute to this important conversation.

	AGENDA	
11:00 AM	Welcome & Housekeeping	Tamar Tchelidze, MD, MPH. Forum for Collaborative Research, UC Berkeley
	Opening Remarks	Helen Rees, MD, MA, MRCGP, University of Witwatersrand. HIV Forum Co-Chair (TBC)
	Summary of Webinar Goals & Recap from Day 1	Veronica Miller, PhD. Forum for Collaborative Research, UC Berkeley
11:15 AM	**SESSION 1: Report from Breakout Rooms 1 - 3 Followed by Discussion**	
	Moderator	Kenneth Mayer, MD. The Fenway Institute. Harvard Medical School
	Rapporteur 1: Acceptable Thresholds for Efficacy (MSM & TGW)	Kimberly Struble, PharmD. U.S. Food and Drug Administration
	Rapporteur 2: Acceptable Thresholds for Efficacy (Cisgender Women)	Charu Mullick, MD. U.S. Food and Drug Administration
	Rapporteur 3: Methods for Deriving Counterfactual Estimate (External Controls); Protocol Design: Screening, Inclusion & Exclusion Criteria	Amy Cutrell, MS. ViiV Healthcare
	Panel Discussion with Rapporteurs	
	SESSION 2: Ethical Considerations	
	Moderator	Rachel Baggaley, MBBS, MSc. World Health Organisation
	Ethical Considerations	Jeremy Sugarman, MD, MPH, MA. Johns Hopkins Berman Institute of Bioethics
	Group Discussion	
	NEXT STEPS	Veronica Miller, PhD. Forum for Collaborative Research, UC Berkeley
1:00 PM	**ADJOURN**	