HIV Post-Exposure Prophylaxis Summit

May 11-12, 2026
Wits RHI Hugh Solomon Hall
57 Klein St, Hillbrow, Johannesburg, 2001, South Africa

Summit Objectives

The workshop aims to accelerate HIV prevention research by building consensus on HIV PEP clinical research that is ethical, efficient, feasible, and acceptable. The summit will consider regulatory perspectives on HIV PEP, the best way to collect efficacy data, alternative clinical trial designs and approaches to collecting data, and discuss single agent PEP regimens in the context of drug resistance and regulatory approval. The working group recognizes the particular importance that African countries and populations have played and will continue to play in HIV research. The workshop will explore the requirements for regulatory approval and guideline development for new regimens through an inclusive approach that incorporates input from academia, community representatives, normative bodies, regulatory authorities, and industry stakeholders. The ultimate objective of the workshop, and working group, is to improve future HIV prevention research and access to new HIV prevention products.

Day 1- May 11, 2026

Local time

*Denotes remote participation

8:30 AM	**Registration & Light Breakfast**	
	Session I: Welcome, Summit Overview	
9:00 AM	Welcome, Housekeeping, Summit Overview	Logan Donaldson, Forum for Collaborative Research
9:05 AM	Introductory Remarks and Goals	Veronica Miller, Forum for Collaborative Research
		Sinead Delany-Moretlwe, Wits RHI
		Helen Rees, Wits RHI
		Ken Mayer, Fenway Health
9:20 AM	Collaborative Goal Setting/Icebreaker	All Participants
	Session II: Sponsors and Funders Updates	
	Moderator: Veronica Miller, Forum for Collaborative Research	
9:35 AM	Gates Foundation Perspectives	Max Lataillade, Gates Foundation
9:45 AM	MSD Perspectives	Paul Schaper, Merck Sharp & Dohme
9:55 AM	Gilead Perspectives	Michael Reid, Gilead Sciences
	Session III: Preclinical Models, PK/PD, and Existing Knowledge	
	Moderator: Ken Mayer, Fenway Health	
10:05 AM	Pre-clinical Models	Gerardo Garcia-Lerma, US CDC
10:20 AM	PK/PD	Charles Flexner, Johns Hopkins University*
10:35 AM	Moderated Discussion	All Participants

11:15 AM	**Break**	
	Session IV: Levels of Evidence; Guidelines and Regulations	
	Moderator: Helen Rees, Wits RHI and Heather-Marie Schmidt, UNAIDS	
11:30 AM	US Guidelines	Rupa Patel, Whitman Walker Health*
11:40 AM	WHO Guidelines	Michelle Rodolph, World Health Organization
11:50PM	EMA Perspective	Maja Sommerfelt-Grønvold, European Medicines Agency*
12:00 PM	SAHPRA Perspective	Boitumelo Semete-Makokotlela, South African Health Products Regulatory Authority
12:10 PM	Panel/Open discussion	All Speakers +
		Farisai Kuonza, Africa CDC
		Adaobi Olisa, Root to Rise
		Jeremy Sugarman, Johns Hopkins University
1:15 PM	**Lunch**	
	Session V: Clinical Trial Designs and Statistical Considerations	
	Moderator: Sinead Delany-Moretlwe, Wits RHI	
2:15 PM	Totality of Evidence	Michael Robertson, BDI Consulting*
2:30 PM	Clinical Trial Designs	Andrew Mujugira, Infectious Diseases Institute
2:45 PM	Statistical Considerations	Deborah Donnell, Fred Hutchinson Cancer Center
3:00 PM	Panel/Open Discussion	All speakers +
		Susan Buchbinder, San Francisco Department of Public Health*
		James Ayieko, Kenya Medical Research Institute
		Michael Reid, Gilead Sciences
		Charles Flexner, Johns Hopkins University*
4:00 PM	**Break**	
	Session VI: Continuation of Day 1 Discussion	
	Moderator: Veronica Miller, Forum for Collaborative Research	
4:15 PM	Moderated Open Discussion	All Participants
5:00 PM	**End of Day 1**	
6:00 PM	**Networking Reception, 54 on Bath, Floor 2**	

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THE FORUM For Collaborative Research℠
Berkeley's Hub for Regulatory Science

Day 2- May 12, 2026

Local time

*Denotes remote participation

8:30 AM	**Registration & Light breakfast**	
9:00 AM	Welcome and Housekeeping	Logan Donaldson, Forum for Collaborative Research
9:05 AM	Introductory Remarks, Recap of Day 1, Goals	Veronica Miller, Forum for Collaborative Research
		Sinead Delany-Moretlwe, Wits RHI
		Helen Rees, Wits RHI
		Ken Mayer, Fenway Health
9:10 AM	Setting the Stage for Day 2	All Participants
	Session VII: Implementation	
	Moderator: Veronica Miller, Forum for Collaborative Research	
9:20 AM	Emergency Care Settings	Fikile Mwelase, South African Department of Public Health
9:30 AM	Pharmacy Based Settings	Kenneth Ngure, Jomo Kenyatta University (JKUAT) & University of Washington*
9:40 AM	Brazil Implementation Settings	Adriano Queiroz da Silva, STI/AIDS Coordination Office, City of São Paulo
9:50 AM	PEP Implementation in the US	Jenell Stewert, University of Minnesota School of Public Health and Hennepin Healthcare
10:00 AM	Panel and Open Discussion	All Speakers +
		Tamara Choola, AFROCAB
		Imelda Mahaka, Pangea Zimbabwe AIDS Trust*
		Andrew Mujugira, Infectious Diseases Institute
		Jerome Singh, University of KwaZulu-Natal
	Session VIII: Regulatory Perspectives	
	Moderator: Veronica Miller, FCR	
10:45 AM	Open Discussion	All Regulators and Participants
11:30AM	**Lunch**	
	Session IX: Brainstorming, Consensus Building, and Proposal Writing	
	Moderator: Veronica Miller, Ken Mayer, Helen Rees, Sinead Delany-Moretlwe	
12:00 PM	Open discussion and Collaborative Writing Session	All Participants
2:00 PM		