Expanding Inclusion for Long-Acting HIV Treatment Trials Workshop

Thursday, 10 November 2022

University of California, Washington Center
1608 Rhode Island Ave. NW
Washington, DC 20036

AGENDA

8:00 AM	**Registration & Light Breakfast**	
9:00 AM	**Session I: Opening & Introductions**	
9:00 AM	Welcoming Remarks from The Forum	Veronica Miller, *Forum for Collaborative Research*
	Welcoming Remarks from NIH Office of AIDS Research	Maureen Goodenow, *Office of AIDS Research*
	Workshop Goals	Nayri Alajaji, *Forum for Collaborative Research*
	Participant Introductions	Nick Murdock, *Forum for Collaborative Research*
9:30 AM	**Session II: Lessons Learned & Opportunities**	
		Moderators: Peter Kim & Jim Rooney
9:30 AM	Lessons From HCV	Greg Dore, *Kirby Institute*
9:40 AM	View from the Trenches: West Virginia	Sally Hodder, *Univeristy of West Virginia*
9:50 AM	Lessons from Other Fields: Psychiatry	Jonathan Liu, *The George Washington University Department of Psychiatry*
10:00 AM	Patient Perspective	*All Participants*
10:10 AM	Moderated Discussion	*All Presenters & Participants*
10:45 AM	**Break**	
11:15 AM	**Session III: Ensuring Access to Long-Acting ARVs -- Pre-Approval Setting**	
		Moderator: Sally Hodder & Joe Eron
11:15 AM	Label, Indications, and Expansion of Indications	Timothy Jancel, *FDA CDER DAV*
11:30 AM	Panel Discussion **(for panelists and ALL)** •What is the optimal time to include patients with adherence challenges into a clinical development program before approval? What are the pros/cons? •What goes into sponsor planning for the lifetime of a drug? •How do we define patients with adherence challenges with regard to: Inclusion/exclusion criteria? Viral load history? Drug resistance? Ability to construct an effective regimen for a comparator arm? •How do we protect patient safety if randomized to an all-oral regimen in an RCT? The potential to cross over to the long-acting arm? If so, when? •What are strategies to recruit patients from rural (not near Centers of Excellence) areas? •What are strategies to for more effective engagement of BIPOC, women, and other underrepresented groups in clinical trials?	*Panelists:* • Timothy Jancel, *FDA CDER DAV* • Martin Rhee, *Gilead Sciences, Inc.* • Cheriko Boone, *TAG* • Vani Vannappagari, *ViiV Healthcare*
1:00 PM	**Lunch**	
2:00 PM	**Session IV: Ensuring Access to Long-Acting ARVS -- Post-Approval Setting**	
		Moderators: Dianne Rausch & Vani Vannappagari
2:00 PM	ACTG 5359	Jose Castillo-Mancilla, *University of Colorado Aschutz School of Medicine* Aadia Rana, *University of Alabama, Birmingham*
2:10 PM	Ward 86 Pilot Study	Monica Gandhi, *Ward 86, UCSF*

	Panel Discussion **(panelists and ALL)**	
2:20 PM	•What is the ideal trial design for post-approval trials? What is needed for a label change? •How are treatment guidelines developed? What type of data is needed? •How do drug labels and treatment guidelines impact reimbursement? •What goes into ADAP formularies?	*Panelists:* • Alice Pau*, NIH-NIAID* • Susan Robilotto*, HHS HRSA HAB* • Rafael Campo*, Merck* • Roy Gulick, *Weill Cornell Medicine*
3:30 PM	**Break**	
4:00 PM	**Session V: Ensuring Access -- All Options on the Table**	**Moderators: Rafael Campo**
	Open Discussion	
4:00 PM	•What other research is needed? •What other networks/organizations could play a role? •Where do we go from here?	*All Participants*
5:00 PM	**Closing Remarks & Adjourn**	**Veronica Miller, *Forum for Collaborative Research***