ILF roundtable
Regulatory pathways and clinical trial design for long-acting PrEP

Organized by the International AIDS Society's (IAS's) Industry Liaison Forum (ILF)
Monday, 5 March 2018, 18:00 – 21:30
Fenway (Ansin Building, 9th floor, 1340 Boylston Street, Boston, USA)

Concept

The International AIDS Society's Industry Liaison Forum is pleased to invite you to a thematic roundtable on "Regulatory pathways and clinical trial design for long-acting PrEP".

Developing long-acting PrEP in the era of oral PrEP
Tenofovir-based HIV pre-exposure prophylaxis (PrEP) is now recognized as a highly effective tool in the HIV prevention toolbox. However, its increasing availability in a number of settings must not prevent the development of new tools, including long-acting PrEP formulations. Indeed, the concomitant use of PrEP by participants in HIV prevention clinical trials can make it challenging to demonstrate the efficacy (non-inferiority) of new tools.

This roundtable will review the latest information on PrEP rollout and provide a state-of-the-art overview of the molecules currently under development as long-acting PrEP and in Phase I, II, and III clinical trials. This will set the stage for an engaging, interactive discussion of remaining challenges and promising approaches for long-acting PrEP clinical trials and regulatory approval in adults and youth (including neonatal prophylaxis).

Objectives of the meeting
The main objectives for this discussion are to:

- Provide an update on PrEP R&D, in particular around long-acting PrEP and clinical trial design for regulatory approval in adult and youth populations
- Provide a multi-stakeholder platform for academia, industry, the community and other stakeholders to exchange on existing and foreseen challenges and potential solutions for the development of long-acting PrEP.

The agenda for this by-invitation-only meeting is available on the following page.

About the Industry Liaison Forum
The IAS Industry Liaison Forum (ILF) works to promote and facilitate the full contribution of the biomedical industry to the global HIV response. By organizing a number of bespoke meetings on key topic areas, the ILF brings to the foreground the contribution of an interdisciplinary group on current and emerging issues. The ILF also builds on its collaboration platform to address a range of issues in paediatric HIV and regulatory affairs. A multi-stakeholder ILF Advisory Group guides this work. Please refer to the ILF guidance on "Key considerations: Compliance with competition rules" (here) for basic rules of engagement for this meeting.

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Agenda

18:00 – 18:45	Light dinner buffet
18:45 – 18:50	**Welcome** *Ken Mayer (The Fenway Institute, IAS Governing Council)* *Cate Hankins (Amsterdam Institute for Global Health and Development)*
18:50 – 19:05	**Opening remarks** *Research – Charles Flexner (Johns Hopkins Medicine, ACTG)* *Community – Mitchell Warren (AVAC)*
19:05 – 19:15	**Update on oral PrEP roll out** *Rachel Baggaley (WHO)*
19:15 – 19:35	**Recent advances in R&D for long-acting PrEP** *Myron Cohen (University of North Carolina School of Medicine, HPTN)*
19:35 – 19:50	Break
19:50 – 20:00	**Recent progress in regulatory pathways and clinical trial design for long-acting PrEP: Framing the discussion** *Veronica Miller (Forum for Collaborative Research)*
20:00 – 20:30	**Roundtable discussion I:** **Long-acting PrEP clinical trials and regulatory approval in adults** *Facilitator: Kimberly Struble (FDA)* *Participants: All attendees*
20:30 – 20:55	**Roundtable discussion 2:** **Long-acting PrEP clinical trials and regulatory approval in youth (including neonatal prophylaxis)** *Facilitator: Bill Kapogiannis (NICHD)* *Participants: All attendees*
20:55 – 21:00	**Summary and closing comments** *Ken Mayer (The Fenway Institute, IAS Governing Council)* *Cate Hankins (Amsterdam Institute for Global Health and Development)*
21:00 – 21:30	Networking reception for continued discussion