ILF roundtable

Regulatory pathways and clinical trial design for long-acting PrEP

Monday, 5 March 2018, 18:00 – 21:30

Fenway (Ansin Building, 9th floor, 1340 Boylston Street, Boston, USA)

Today's topic

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<u>Developing long-acting PrEP in the era of oral PrEP</u>

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).

Today's objectives

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- 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.

Today's 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

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Rules of engagement

Key considerations: Compliance with competition rules

What to avoid

- **Do not** discuss with other participants competitively sensitive information on anything relating to topics such as prices, discounts, margins, price-related contractual terms or territorial protection.
- **Do not** exchange information on costs, capacity, business plans or commercial strategy. The only exception is for industry data that are publicly available via data services, such as interest rates.
- **Do not** exchange individualized information on output plans.
- **Do not** engage in conduct that could have the effect of restricting competition by excluding actual or potential competitors from the market or preventing them from competing effectively.
- **Do not** discuss matters relating to your company's marketing plans, design, production or distribution.
- **Do not** share with other participants any other competitively sensitive or confidential information.

What to do

- **Do** report to the IAS any discussion or conduct that you suspect might violate these guidelines, and keep a copy of such correspondence.
- **Do** leave any discussion that you feel might infringe these guidelines, and ask for your leaving to be recorded in the minutes.
- **Do** refuse any commercially sensitive or confidential information you might be offered. If you receive such information, return them immediately, emphasizing that you do not want to have access to them. Keep a copy of such correspondence.
- **Do** remember that you are responsible for your own compliance with these guidelines.

Creating a safe space for discussion

- Active participation
- Neutral analysis
- Constructive comments

Housekeeping instructions

- Introduce yourself (name, affiliation) before speaking

- Speak through the microphone