



THE FORUM
For Collaborative ResearchSM

HIV Treatment bNAbs: Clinical Research Considerations Washington DC

Monday, October 30, 2023

The meeting will resume at 3:00pm Eastern.

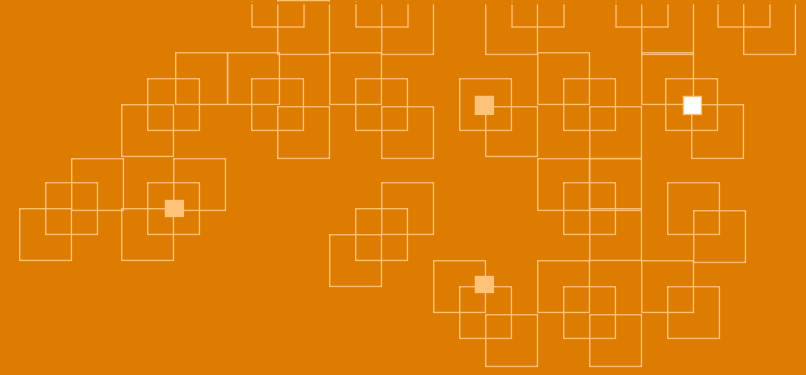


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HIV Treatment bNAbs: Clinical Research Considerations

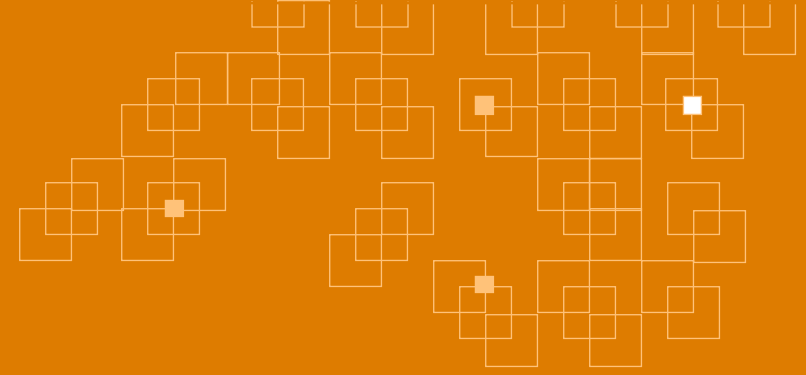
Washington DC

Monday, October 30, 2023



Welcome, Housekeeping, and Forum Overview

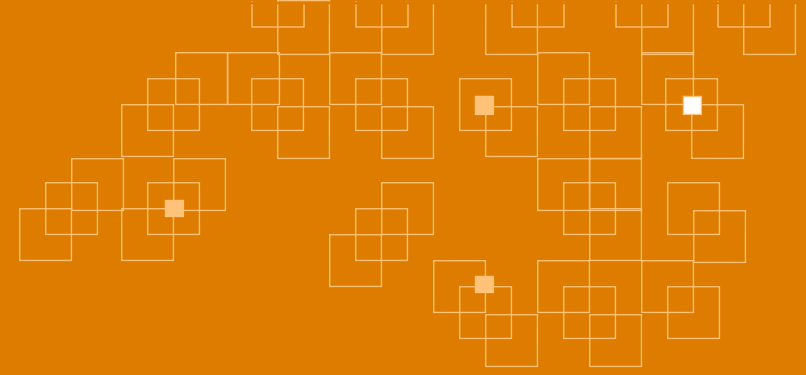
Nick Murdock, *Forum for Collaborative Research*



Housekeeping

Please Note

- Breakfast, lunch, and drinks will be available in the lobby
- Bathrooms are located outside the back right doors, near the coatrack
- There are Zoom participants, please speak into a microphone so they can hear you
- All microphones are on at all times
 - Private conversations should be held in the lobby or hallway
- This meeting is being recorded for notetaking purposes, and the recording will not be distributed or posted



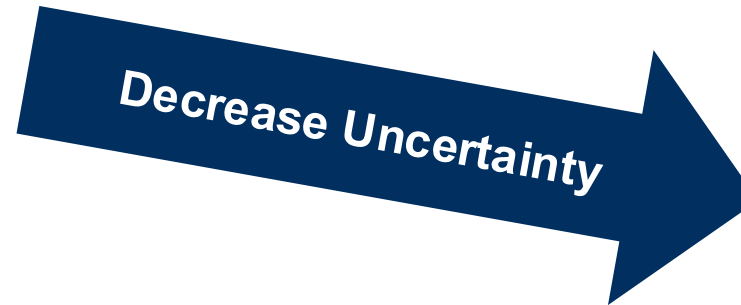
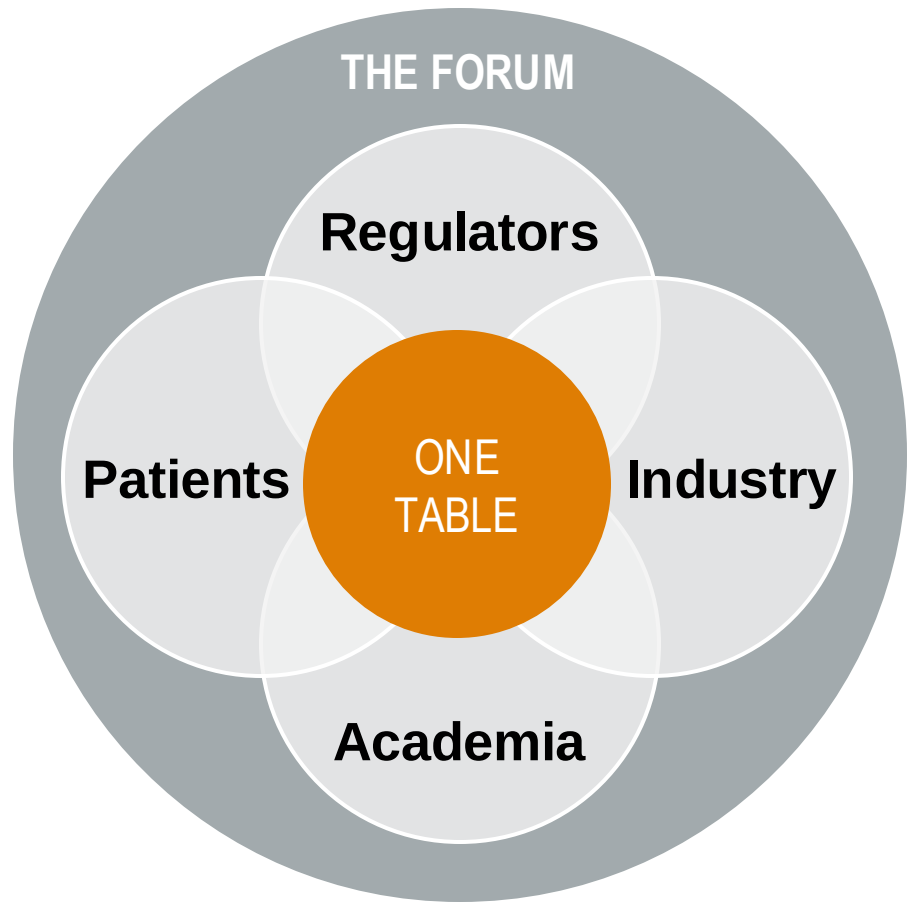
Forum Overview

Overview of the HIV Forum

- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate treatment and prevention development for HIV
- **How:** provide a neutral, independent, safe space for discussion and deliberation across stakeholder groups
 - Focus on developing consensus, increasing synergy and collaboration, and reducing duplication and uncertainty
 - Ongoing working group activity throughout the year anchored by larger project events
 - Active & engaged participation



The Forum's Concept



- Enhanced clarity
 - Innovation
 - Collaboration
-
- Redundancy
 - Development time
 - Risk

Forum Operating Principles

- Independent and neutral venue
 - Ongoing multi-stakeholder dialogue
 - Each stakeholder group has an equal voice
- Facilitate best science-based decisions, in real time
 - Break down inefficiencies and redundancy
 - Increase clarity, collaboration and innovation
 - Benefit to whole field, especially patients

Forum = Safe Space

- Closed meeting
 - No marketing
 - No press
- Bring your expertise
 - Leave your “hat” at the door

Rules of the Room and Zoom



What's said in the room stays in the room

What's said in the room is not for attribution

Let the science speak

Active participation

HIV Forum Sponsors



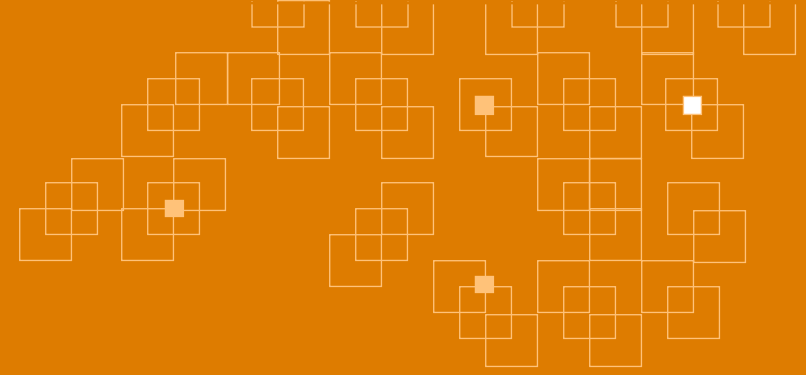
With Additional Support for the PrEP Project from:

BILL & MELINDA
GATES *foundation*

Forum Team



- Veronica Miller – Director
- Christopher Berry – Events Manager
- Donnice Butler – Senior Administrative Assistant
- **Nicholas Murdock – Research Associate**
- Mitchell Leus – Research Associate
- Shilpa Mitra – Research Associate
- **Logan Donaldson – Research Associate**
- Sehyr Khan – Research Associate
- Azza Karrar – Senior Research Associate
- Alicia Jellinek – Program Financial Analyst
- Chris Hoffman – IT and Operational Director
- Margot Yann – Lead Data Scientist
- Zachary Rooney – Research Associate
- Sammy Berman – Research Data Analyst
- **Robin Schaefer – Post-Doctoral Researcher**
- Jeffrey S. Murray – Program Advisor
- John Sninsky – Program Advisor
- Alessi Ayvaz, Undergraduate Student Researcher



Introductory Remarks and Overall Project Goals

Veronica Miller, *Forum for Collaborative Research*

Overview of the bNAbs Project

- Broadly neutralizing antibodies (bNAbs) appear to be a promising product for HIV treatment and potentially prevention in certain cases
- bNAbs have been approved for other disease areas and are becoming increasingly common on the market, though not yet in the context of HIV treatment
- HIV viruses have unique characteristics that pose questions for approval

Overview (Continued)

- The Forum was approached by stakeholders in 2022 to convene around these regulatory questions as HIV treatment bNAbs enter later stage clinical trials
- Many lessons can be learned from previous generations of ARVs
- How do we approach clinical trials and diagnostics for HIV treatment bNAbs clinical trials?
- This will be the first of several convenings on these regulatory questions to build consensus around bNAb trial designs

Framing Today's Discussions

- In order to have a productive discussion, we have limited some parameters of today's workshop
- We will be mainly US-focused for today
 - International regulatory considerations will be covered in subsequent meetings
- Today we will discuss late-stage clinical trials for bNAbs in the context of adult HIV treatment
 - bNAbs for post-natal prophylaxis, pediatric treatment, and prevention uses will be discussed at subsequent Forum workshops
 - Implications for HIV reservoir reduction or cure research can also be addressed at later workshops