Enhancing Community Engagement in HIV Prevention Clinical Trial Design: Insights from AVAC's Clinical Trial Design Academy

G. Kumwenda, , N. Sikwana , D. Ouya , D. Nhamo , N. Yola , S. Hannah , M. Warren
AVAC, Malawi, AVAC, South Africa, AVAC, Kenya, Pangea Zimbabwe, Zimbabwe, Desmond Tutu Health Foundation, , South Africa, AVAC, United States

EP0660

Background

Community Engagement (CE) has been instrumental in shaping HIV prevention research, but its influence on clinical trial design remains underexplored. To address this gap, the Clinical Trial Design Academy, supported by AVAC, aims to empower advocates with the knowledge and skills to more vigorously shape next-generation clinical trial designs. Specific objectives of the academy include to:

- Build the capacity of a new cadre of HIV prevention advocates in and beyond AVAC partnerships to engage in next-generation HIV prevention clinical trial designs.
- Establish mechanisms for cross-collaboration and strategy development among pharmaceutical companies, advocates, regulators, researchers and other key stakeholders.
- Identify and elevate key issues related to next-generation clinical trial design

Description

AVAC identified 20 advocates from nine African countries based on their interest in clinical trial design. The program began with three foundational virtual workshops focusing on (1) fundamentals of HIV prevention clinical trials, (2) innovative trial designs in the PrEP era, and (3) regulatory guidance for externally controlled trials. An in-person workshop followed, where participants consolidated learnings and priorities. Participants engaged with researchers, statisticians, and scientists, exploring new trial design approaches, such as identifying and using appropriate active controls, and use of hypothetical placebo measures such as background HIV incidence data, recency assays, registrational cohorts, and biomarkers. Participants also deliberated on the implications of conducting prevention trials in the context of choice of existing, effective HIV prevention products.

Figure 1: In-person Clinical Trial Design Academy Workshop in Salima Malawi

Lessons Learnt

The Academy identified key community priorities for the design and conduct of future HIV prevention trials as outlined below:

- Novel trial designs must meet rigorous scientific validity standards while addressing other critical factors including drug-drug interactions and gathering data on pregnancy and lactation. Pharmacokinetic studies should explore protection onset, forgiveness, and drug tail effects.
- Trials must represent diverse geographies and populations, including key groups like people who inject drugs (PWID), and assess acceptability, choice, and persistence.
- Trials should reflect the principle of choice, offering product options in different phases of research including during, and after trials.
- Participants must be supported to understand how designs impact them; consent must be ongoing, revisited at key decision points
- Materials should be language-appropriate, culturally relevant, and include visual or storytelling-based tools. True consent means informed, voluntary, and understood
- HIV prevention trials must prioritize access, equity, and community relevance. No product should advance to efficacy trials without a clear plan for post-trial manufacturing, pricing, and equitable access.
- Future trial designs should be adaptive and flexible, incorporating lessons learned from past studies through community research mapping. Build on the extensive lessons learned to continually refine and adapt clinical trial designs, ensuring alignment with ethical guidelines and the needs of communities.

Conclusion

The work of the clinical trial design academy marked a significant step forward in equipping African-based advocates with the tools and knowledge to meaningfully influence the future of HIV prevention research. By centering community voices and ethical considerations, the Academy is poised to play a pivotal role in shaping next-generation clinical trial designs. In 2025, the Academy will continue monitoring the inclusion of community priorities in the monthly oral PrEP trial design and contribute to the design of upcoming and future clinical trials. The Academy will further launch an online resource hub to provide advocates with real-time information and tools for continued engagement in clinical trial design, thereby making clinical trials more relevant to the communities they serve.

Presented at IAS 2025, the 13th IAS conference on HIV Science

AVAC
Advocacy. Access. Equity.

IAS 2025
13–17 July