



IAS Corporate Partnership Programme

Towards HIV Cure: Industry Collaboration Group

Africa HIV cure research: Strengthening industry-community engagement in clinical research

AIDS 2022, Montreal, Canada
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Satellite report
12 August 2022



Background

Although antiretroviral therapy (ART) can efficiently control HIV and improve the lives of people living with HIV, treatment requires life-long adherence, which is challenging for many people due to a host of factors. An HIV cure could overcome the limitations of ART, reduce new HIV transmissions, stigma and discrimination, and provide a sustainable financial solution to end the epidemic. Efforts to coordinate HIV cure research engagement and advocacy have emerged through formal partnerships between academia and industry. Engaging communities in this effort remains

an imperative, especially in regions of Africa, which bears the burden of HIV prevalence. Increasing knowledge dissemination, building capacity for advocacy and increasing involvement of end-users into the strategy and design of cure research are key to ensuring acceptability, scalability and cost effectiveness of HIV cure research interventions. This satellite explored how best to engage and involve communities of people living with HIV in end-to-end product development and, in particular, clinical research in Africa.

Satellite programme

Welcome Alan LANDAY , Rush University Medical Center, United States
Introduction Jan VAN LUNZEN , ViiV Healthcare, Germany
Overview of the IAS HIV Cure Strategy: importance of doing cure research in Africa Sharon LEWIN , The University of Melbourne, Australia
Strengthening industry-community engagement in clinical research: Lessons learnt from HIV prevention trials Nandi LUTHULI , AVAC, United States
How clinical research is involving communities Thumbi NDUNG'U , Africa Health Research Institute, South Africa
Industry needs and current approach to community engagement Devi SENGUPTA , Gilead Sciences, United States
Panel discussion and Q&A Bonnie HOWELL , Merck, United States Izukanji SIKAZWE , Centre for Infectious Disease Research in Zambia, Zambia Thumbi NDUNG'U , Africa Health Research Institute, South Africa Jan VAN LUNZEN , ViiV Healthcare, Germany Josephine NABUKENYA , Uganda Marina CASKEY , The Rockefeller University, United States Jeffrey SAFRIT , ImmunityBio, Inc., United States Alan LANDAY , Rush University Medical Center, United States Timothy HENRICH , UCSF, United States
Closing remarks and co-chair handover Bonnie HOWELL , Merck, United States Jan VAN LUNZEN , ViiV Healthcare, Germany Alan LANDAY , Rush University Medical Center, United States Timothy HENRICH , UCSF, United States



Key points from the presentations

Alan Landay opened the satellite by setting out the aims of the session: to explore barriers and facilitators to the meaningful engagement and participation of communities in industry-led HIV cure research to ensure acceptability, scalability and cost effectiveness of HIV cure research interventions, especially in Africa.

Jan van Lunzen introduced the satellite with a description of the role of the IAS Cure Group, stressing the importance of meaningful community engagement in cure research. He emphasized that effective treatment is not always accessible in low- and middle-income countries and there is a need to invest in cure research. The Cure Group aims to enter into a dialogue about equality and fairness to ensure that a cure is affordable, scalable and accessible in low- and middle-income countries. A real dialogue is needed between high- and low- and middle-income countries that involves equal rights and equal voices among stakeholders.

Overview of ongoing cure research strategy and why doing research in Africa – Sharon Lewin, Australia

Sharon Lewin presented an overview of the third iteration of the IAS HIV Cure Strategy published in 2021, including research priority areas, and the Target Product Profile for HIV cure, which underpins the research. The burden of disease dictates that cure research should take place in Africa.

Specific issues should be addressed in the African context, such as what people will want from a cure, how much it could cost to be implemented, what can be applied in non-healthcare settings and what will be acceptable to communities. In addition, there are specific scientific issues to be addressed, for example, what impact HIV subtypes will have on cure effectiveness, whether host factors (genetics) dominant in African populations play a role, and whether common co-infections and chronic inflammation have an impact on cure interventions, especially on the use of immune therapy.

There will be unique challenges to address, Lewin said, and with new technologies (LA-ARVs), we should avoid repeating what happened with access to treatment when it became available. She introduced the HIV Cure Africa Acceleration Partnership (HCAAP), created specifically to address these implementation challenges. Strengthening HIV cure research in Africa is a top priority because of the distinct characteristics of HIV in Africa and the need to reduce any possible delays in the implementation of an effective cure.

Strengthening industry-community engagement in clinical research: Lessons learnt from HIV Prevention trials – Nandi Luthuli, United States

Nandi Luthuli started by reminding research stakeholders of the Good Participatory Guidelines (GPPs) developed in response to controversies about PrEP trials in 2003. These provide systematic guidance to engage with communities for the conducting of HIV prevention clinical trials. She emphasized the importance of research literacy, which should be a bidirectional process between researchers and communities, grounded in a shared language and literacy.



Community engagement has been a hallmark of clinical research and product development. She noted the increasing engagement of industry with communities based on the GPP guidelines and described several examples. Activities include early engagement in the process, customized GPPs, protocols and conducting of the trial informed by community members, and the creation of global community advisory groups and a trial design academy. Luthuli noted that research is a process and that it is important to keep in mind that issues are not about one particular trial, product, community or issue. Also, because of today's interconnectedness, all research enterprises can be affected by what is happening in one trial.

A key lesson is that GPPs are not about the community of practice; they are about stakeholders' practices and relationships between stakeholder groups, as well as ongoing durable relationships that transcend one trial or one product. It is also necessary to engage early and often enough to ensure that communities are meaningfully part of the process. Failure to do so may lead to people not using the product. Luthuli pointed to the Delaney collaboration that was seeing communities as a core pillar alongside industry to build sustainable programmes and partnerships from the earliest phases of the research. Engaging early with communities is important to mitigate changes in the research. Finally, conducting social and behavioural research is also important.

How clinical research is involving communities – Thumbi Ndung'u, South Africa

Thumbi Ndung'u spoke about the need for an ongoing dialogue between stakeholders and the importance of cure research based on ongoing prevalence and co-morbidity data. He described community engagement in the FRESH study, which involves young women aged 18-23 and combines basic science research with a social empowerment programme. Work with the community has been extended to institutions and building infrastructure and networks. The research also involves young scientists from the area.

Industry needs and current approach to community engagement – Devi Sengupta, United States

Devi Sengupta presented an iterative process that could lead to an HIV cure. Time and commitment will be needed, and the process must be done in strong partnership with communities and be built around trust and collaboration to enable the innovation to reach our goal. She highlighted the need to find allies across sectors, for example, internal partners, academic partners, regulatory partners and activists and advocates, globally and locally.

She described community engagement goals that start by affirming the priorities of the community, engaging those most affected early and throughout, building transparency and trust, getting insight and feedback to improve the research programme, and ensuring timely communication of the research. This must be done by fostering an environment of dialogue and collaboration. Gilead established an HIV Cure Global Community Advisory Board (CAB) in 2021 with the main mission of meeting quarterly to get input on the overall programme and specific questions about trials. The CAB covers a range of topics and Sengupta shared some of the feedback from CAB members, part of which is foundational to the research and will increase the probability of success of the cure research programme.



Sengupta provided examples of engagement activities in a Phase 2a study in South Africa. These included regular meetings with investigators during protocol development, formal review of informed consent forms, focus groups and nested socio-behavioural research studies. She concluded by saying that science is better when everybody has a seat at the table. Early, frequent and repeated engagement is necessary for the success of the research.

Panel discussion

Jan van Lunzen opened the panel discussion by asking what the industry should do or do better. Josephine Nabukenya stressed the importance of early involvement of communities in the research and of communicating about the research. Many people do not know that products are being developed. Key people should be identified to be links between researchers and the community.

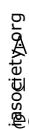
Bonnie Howell commented on the importance of engaging communities in Africa and, in particular, in cure research as the level of engagement has not been at the same level as that for treatment and prevention research. Cure research comes with its own challenges and there are still some concerns around trust and how industry can partner with communities. This may be more challenging in the cure space and requires robust engagement, as well as ensuring that the interest and concerns of the community are at the forefront of the research agenda.

Jeffrey Safrit commented on the study conducted by ImmunityBio in southern Africa, which also included setting up manufacturing and training scientists and technicians. Combined, this approach allows for broad engagement and a better chance of success for the research. Izukanji Sikazwe pointed to the need for more African leadership and voices to talk about cure research. There is a need to think about the community beyond people living with HIV; it should include civil society, churches, governments and academia, which are all part of the community in which interventions are developed. It is equally important to remember that there were 54 countries in Africa and therefore many different communities to engage with. HCAAP is in a transition period, working with WHO and the Africa CDC to transition and broaden the platform to have more African involvement and engagement and go beyond HIV (for example, to include sickle cell disease).

Tim Henrich commented on the lack of infrastructure in Africa, pointing to inequity across the world in conducting research. Jessica Salzwedel from AVAC noted that through the Delaney collaboration, it has been possible to establish some infrastructure. This programme also enables community engagement and transparency. How can industry do the same?

Questions from the audience

An audience member asked about viral diversity at subtype level and its impact on cure research, especially in the context of bnAbs. Marina Caskey commented that some antibodies used for cure research are isolated from people in Africa and that research can learn from diversity, for example, to understand what combination of antibodies is needed to move forward.

 An audience member called for a GPP specific to cure research and for gaining a better understanding of the needs of young women. She also called for investing in community education that is locally appropriate and for real innovation in how we communicate cure



research in Africa. Josephine Nabukenya added that we should also look at how information is delivered (for example, online for young people) and that we should also know where our target audiences are and how they access information.

An audience member called for greater involvement of Africans in the Global CAB. Current CABs should be more representative, he said, and called for more diverse voices. The audience member noted that AfroCAB was founded for that purpose. It would make sense to build on existing CABs and further develop them (ACTG, for example), instead of starting new ones from scratch.

Thumbi Ndung'u commented that much more can be done, but this was the start of a dialogue. Sharon Lewin added that many people are currently being trained through the IAS-AVAC Cure Academies (120 trained to date). This is only a beginning, and more funding is needed (Lewin noted that current IAS-AVAC academies are partially funded by industry).

An audience member from the [Global Gene Therapy Initiative](#) said that the best way to engage communities is to encourage economic development, which is what several small biotech companies are doing. She asked why more established companies decide that it makes more sense financially to keep up the donor recipient relationship than invest in the local community. Devi Sengupta commented that there is no downside to investing locally. Jan van Lunzen added that more work should be done in the region while supporting local scientists, pointing to the FRESH cohort as an example of a real partnership that includes researchers. Bonnie Howell spoke about her company's investment in local research through investigator-initiated programmes. Engagement is also about understanding needs.

An audience member pointed to the need to build strong research and industry in Africa and change the thinking that the answers should come from outside Africa.