



January 2024

Unitaid's Community Advisory Board model
Putting people at the centre and engaging communities

Introduction

People are at the centre of Unitaid's [Strategy 2023-2027](#), highlighted through the vision of equitable access to health innovations to ensure healthy lives and promote well-being for all and Strategic Objective 3 (SO3) to foster inclusive and demand-driven partnerships for innovation, including:

- Maximizing engagement of affected communities and responsiveness to their needs, which is measured by KPI 3.1 Partner Satisfaction - the extent to which Unitaid has successfully established effective and inclusive partnerships – with Communities and Civil Society, Scale Funders and Countries.
- Maximizing alignment and synergies with governments, in-country stakeholders, affected communities and civil society organizations is measured by KPI 3.2 Effective engagement with CCSE - the extent to which there is effective engagement with affected communities and civil society and responsiveness to address needs.

Unitaid occupies a unique place in global health: Championing equitable access to health tools and ensuring that innovative health solutions are fit-for-purpose, affordable, and rapidly available for people and communities who need them most.

This document is developed to provide a broad overview of the Community Advisory Board (CAB) model across Unitaid-funded projects as guidance for project stakeholders providing examples of what others have done and the chance to learn from varied experience. For some grantees a CAB may have been planned or proposed as part of the project and for others they may have been asked to add a CAB to the project. The aim of Unitaid's Community Advisory Board Model Brief is:

1. To learn about CAB options for projects - CABs linked to clinical trials or other CABs with more of a focus on supporting product introduction and creating demand.
2. So that others may learn from the partners and experiences referenced.

Community Advisory Boards (CABs)

CABs are a type of advisory board, consisting of representatives of affected communities who meet to share information, lessons, and learnings. CABs are an aspect of community-based participatory research with origins linking to clinical research, discussions on ethics and human subject research.

[CABs were first developed as part of the HIV response](#), and have since been adapted and adopted by Tuberculosis (TB) and in other disease responses. A CAB was initially defined as a group of community members who represent the global or local population(s) impacted by HIV/AIDS. They worked closely with the network and/or site investigators and research staff to provide a community perspective into research plans and studies. In fact, CABs have a role to play at each stage of research, from setting the research agenda and determining priority questions to reviewing protocols to overseeing trial contact to disseminating results.

Over the past 30 years, CABs have played an increasingly more prominent role alongside ethics committees "in protecting populations" and in promoting research within communities and thereby increasing the "value proposition" or "social value" of global health research. CABs initially focused on advising researchers and research networks. Increasingly, CABs are beginning to work across the spectrum of research, end-to-end, and addressing issues such as demand creation, policy translation, treatment literacy etc. Indeed, it is at this juncture that Unitaid along with partners are supporting, promoting, and expanding the role of CABs within the range of Unitaid programme priorities and their related projects.

Why potential Unitaid Grantees should consider including CABs in proposals and programmes

CABs have the proven potential to create more inclusive and informed community responses to meet programme objectives and maximize the impact and longer-term outcomes of the grants. CABs can be shaped to foster engagement with communities and civil society groups to inform decisions, improve

understanding about new products, increase demand and co-develop product adoption and roll-out strategies and can provide strategic direction and leadership to strengthen community engagement, increase demand generation, and ensure that the project supports and complements the activities of the global community.

Unitaid's CAB model is being implemented across several areas of work aiming to improve access to critical tools HIV, TB, COVID-19, and postpartum haemorrhage as a flexible way to engage with communities with a focus on advocating for health products and to support project objectives. With CAB members and their networks providing a robust understanding of their community and the ability to contribute valuable insight that can lead to more effective research, programming, and policymaking.

Some examples of CABs in Unitaid funded programmes include:

- In the context of **HIV**: The Clinton Health Access Initiative (CHAI) Optimal CAB (2016-2022, see box below) and the Scaling up optimized second-line combination antiretroviral therapy for HIV patients who have failed first-line treatment ([D2EFT trial](#)) CAB (2017-2021).
- In the context of **TB**: Strengthening Paediatric TB services for Enhanced Early Detection ([TB-SPEED](#)) (2017-2021), Better Evidence and Formulations for Improved MDR-TB Treatment for Children ([BENEFIT Kids](#)) (2019-2022), and Adherence Support Coalition to End TB ([ASCENT](#)) (2019-2023).
- In the **COVID-19** response: [ANTICOV Platform Trial](#) - An open-label, multicentre, randomised, adaptive platform trial of the safety and efficacy of several therapies, including antiviral therapies, versus control in mild/moderate cases of COVID-19. The Community Advisory Group (CAG) provide a vehicle for effective community input.
- In the context of **post-partum haemorrhage (PPH)**: CABs are being developed and/or considered across the portfolio.
- For **Long-Acting Technologies (LAT)**: In 2021, the [Long-Acting Technologies Community Advisory Board \(LAT CAB\)](#) was established and is coordinated by Treatment Action Group (TAG) and the AfroCAB Treatment Access Partnership to ensure community engagement with researchers working on the development of long-acting technologies under the Unitaid-funded LONGEVITY project including people with lived experience with malaria, TB, and HCV with strong civil society and policy experiences who may benefit from the development of long-acting medicine. The partners will coordinate and co-chair this new global, cross-disease LAT CAB. LAT CAB is a dedicated community body aiming to advance LAT research and uptake under the Unitaid-funded [LONGEVITY project](#) which aims to develop long-acting technologies for TB and malaria prevention, and a cure for the HCV.
- In the context of **HCV**, and in a first for any Unitaid Portfolio of Projects, the HCV Portfolio Community Advisory Board (HCV Portfolio CAB) was established from May 2023 onwards to ensure that the voices, perspectives, and expertise of communities from across the entire portfolio inform all stages of the process and that communities are engaged from the outset (see Annex 2 Overview and Annex 3 ToR). The HCV Portfolio of Projects provides an excellent example of how community engagement can and should be approached and done. The standout measure included under "Call scope" was to clearly state upfront the case for engagement with civil society and affected communities. Specifically:

Engagement with civil society and affected communities is a critical determinant for success. Proposals should clearly indicate the role of and collaboration with affected communities and civil society. Meaningful engagement with civil society and affected communities should be included across proposed activities, for example integration of community and civil society into project implementation or governance.

Optimal Community Advisory Board, as part of Unitaid's grant to CHAI

The Optimal CAB was established in 2016 as part of the Unitaid ART Optimization Portfolio (specifically, the [Optimal grant](#)) to help with user awareness and demand creation. The Optimal CAB, which was a CHAI/AfroCAB partnership, aimed to strengthen community engagement in product adoption, ensuring smooth transition and roll-out of new products, fostering demand and understanding of ARV commodities and ensuring the voices of people living with HIV

were at the centre of decision making. The Optimal CAB also played a role in supporting advocacy for equitable access to DTG-based regimens.

Optimal CAB members have enhanced HIV treatment literacy and generated demand for antiretrovirals and advanced HIV disease (AHD) commodities, including:

- In [Nigeria](#) where the CAB organized national stakeholder meetings to translate findings on weight gain related to antiretroviral treatment into national policy following the Kigali women's meeting and trained community members in seven states to serve as leads to scale up community engagement at health facilities.
- In [Uganda](#) where CAB members participated in the national AHD technical working group, directly contributing to national-level implementation, and hosted two central community trainings which helped solidify AHD as a priority within communities of people living with HIV.
- Through a CAB virtual meeting for adolescent girls and young women from several project countries to disseminate antiretroviral therapy guidelines for dolutegravir.

In addition, in 2020, the Optimal project partners (CHAI and AfroCAB) launched a [community consultation and webinar series](#) to inform community partners about accessing HIV care and treatment during the COVID-19 pandemic and provide a forum for people living with HIV to share their insights and experiences and identify community-based solutions and strategies to address access challenges. For further details about the Optimal CAB, see *Annex 1*).

HCV Portfolio Community Advisory Board

In 2023, Unitaïd announced a [US\\$31 million investment in harm reduction efforts to prevent hepatitis C \(HCV\)](#) among people who inject drugs and others at high risk implemented through three complementary projects by [Frontline AIDS](#), [Médecins du Monde](#), and [PATH](#) over four years with a one year inception phase. Unitaïd's funding is to facilitate the piloting of two innovative and under-used products – notably low dead-space syringes (LDSS) and long-acting depot buprenorphine (LADB) in 10 countries; and demonstrate the integration of HCV prevention, testing and treatment in harm reduction services and/or prisons. The projects will also generate evidence critical to enabling the broader use of these products, including understanding user preferences, addressing high costs and increasing demand.

In a first for any Unitaïd programmatic priority portfolio of projects, an HCV Portfolio CAB has been established to ensure that the voices, expertise, and the perspectives of community from all the projects inform all stages of the process and that community is engaged from the outset. As such, the purpose of the HCV Portfolio CAB is to contribute input, engagement, and participation to the ethical monitoring, implementation, and evaluation of the HCV Portfolio research projects to ensure that the lived/living experiences and feedback of people who use drugs inform the study and that the work contributes to improved access to HCV prevention.

In the six months from May-October 2023, the HCV Portfolio CAB Terms of Reference (ToR) were developed and finalized, the nomination process for CAB members was undertaken and completed, the Master Research Protocol Review Framework was developed, and five CAB meetings were organized and held including: 1. Project Orientation and Protocol Review Capacity Building, 2. Low Dead-Space Syringes/Needles (LDSS/N) Master Research Protocol Review, 3. Long-Acting Depo Buprenorphine (LADB) Master Research Protocol Review, and 4. HCV Models of Care (MoC) Research Protocol Reviews (Consortium-based CABs), as well as 5.- one meeting in which some participants met in person and were able to see programmatic examples of LDSS/N and run through FGD tools together.

While it is still early days to assess the impact of the HCV Portfolio CAB; to date it appears to be a strong example of start-/end-to-end community-led/involved participation.

For further details about the HCV Portfolio of Projects see *Annex 2 Overview* and *Annex 3 ToR*.

Inclusion of community advisory boards within Unitaïd grant applications and programmes

1. The principles for creating a community advisory board:

Creating and maintaining a CAB may require substantial time, effort, and resources from both grantees and CAB members. It is important to understand that initiating and maintaining an optimally functioning CAB is time-consuming and resource intensive. By creating a CAB, the lead organization is agreeing to participate in an ongoing collaborative relationship with members of communities.

If the lead organization cannot support a CAB, it may be better to explore other options, for example:

- (1) engaging partners with expertise in forming and managing CABs; or
- (2) assessing other forms of community engagement such as through social media, community forums or listening sessions, surveys or focus group discussions to learn about specific community perspectives; or
- (3) working with and investing in existing CAB mechanisms. This would not entail as much time, effort, and resources as "creating a maintaining a CAB" (described in the above paragraph) but would offer a sort of middle path between creating a CAB, engaging other partners with expertise in forming a CAB (1) and "assessing other forms of community engagement" (2).

2. Key questions and considerations:

- Managing and setting up a CAB – How will the CAB be staffed? How will the CAB's input be incorporated into implementation of the project? Some Unitaid grantees have opted for south-based community leaders, who are experts, providing technical support to select and manage of members and meetings. Consider multi-site projects need for CABS at both global and country levels. And how are they linked, and should there be an agreed hierarchy?
- CAB membership – How will community advisory board members be recruited? Outline the process for selecting members in the Terms of Reference (ToR) and include criteria and any qualifications for membership, duration of appointment, financial matters, process for appointment and diversity of members, including key and vulnerable and criminalised populations. How will the demographics of the project country be represented by the membership, along with their background, experience, skills, and perspectives? Representation from communities of people who face stigma and discrimination or who are marginalized or underserved by health programs is critical to building a strong CAB. Members must be willing to provide honest feedback about the potential impacts of the proposed activities on their peers. It is also important to identify relevant community organizations that should be represented on the CAB. How will communities be involved in the membership selection? When working with members, it is important to consider that some people may be open about their lived experience outside of their country of residence but may not have shared within the communities they live.
- Support meaningful participation - Consult with CAB members when setting meeting times, frequency, locations, and modalities, acknowledging that preferences may vary by community. Involve CAB members in determining agendas. Collaborate to develop and set expectations for respectful and safe conversations. Consider including team-building activities in the initial CAB meetings. Indemnify CAB members for any out-of-pocket expenses incurred when they participate in work related to the CAB. This could take the form of reimbursement of any out-of-pocket expenses such food or transport or providing food or transport directly. Also consider communication stipends if frequent online CAB meetings are scheduled. Work with members to identify other barriers to participation and how to address them.
- Provide members with technical knowledge necessary to weigh in on policy matters and to navigate grant making structures and requirements - Upon appointment, many CAB members may not have a sufficient understanding of grant-related technical and operational issues, which can hinder their ability to participate in deliberations. Frequent capacity building sessions should be set up either physically or virtually, depending on the resources available, and be part of the CAB work plan. Grantees can and should provide CAB members with a baseline understanding of grant-related technical and operational issues. External advocates can be consulted or invited to present during meetings to provide a broader range of perspectives. It is important that CABs both equip members with the knowledge and information they need to engage technically on an issue and help CABs navigate grant making structures and requirements.
- Ensure members do not suffer from participation fatigue or burnout - Even with a clearly understood mandate and committed CAB members, there can be an issue of participation fatigue. To mitigate against burnout and absenteeism, members should serve set terms. There should also be agreed-upon rules regarding members' absences or lack of participation, so that inactive members can be replaced.

- Establish boundaries for all CAB participants - Create a safe space for participants to provide honest critiques and to highlight issues with grant implementation. Members should not be censored or penalized for providing their views or advice. Clarify that even though every idea will be heard, not every idea will be implemented or acted upon. These safe spaces need to ensure the safety and/or confidentiality of CAB members especially on matters involving criminalized, key and vulnerable populations along with those sensitive political, social and other issues which may result in tensions and/or conflicts over policies and laws, political party platforms, and the country's current situation and direction.
- Compensate members for expertise - Value members' time and expertise through honoraria, travel support, per diem and/or funding for related project activities within the limitations of the project countries. Collaborate with CAB members to determine appropriate compensation and explain clearly about duration including when and how this funding will come to an end. Project leads should also consider opportunities for responsible transition of the CAB and its membership (as applicable).
- Ensure the CAB is well resourced - When grantees are committed to a formal advisory model, the proper resources need to be allocated for administrative staff, an operating budget, and a workplan. CABs cannot operate effectively on the labour of volunteers alone. CABs are much more likely to achieve their potential when even a small amount of funding and resources are dedicated to support operations. Having dedicated personnel available to publicise upcoming meetings, set agendas, take notes, and help facilitate conversations can make a significant difference. Unitaid projects have provided funding for CAB members to travel to meetings and conferences with per diem provided. Funding has also supported members with in-country community engagement activities.

3. CAB Terms of Reference – Create clearly defined ToRs and operational procedures

CABs should have terms of reference that clearly outline the purpose of the CAB, members' roles and responsibilities, membership (including criteria, qualifications, and appointment duration), financial matters, methods of operation and appointment procedures. For examples of terms of reference for CABs, see:

- [CHAI Optimal Community Advisory Board Terms of Reference ToR published 2016.](#)
- WHO/HRP RfP - [CAB for the WHO Postpartum Haemorrhage Treatment trial \(2022-067 UHL-SRH CABTreatmentTrial\)](#) published in November 2022 to engage an expert third party to support the project CAB
- LSHTM (Tranexamic Acid Access For All Mothers With Bleeding After Childbirth) TRANSFORM project Community Advisory Board Terms of Reference published 2022- *see Annex 4.*
- D²EFT Community Advisory Board Terms of Reference published - *see Annex 5.*
- HCV Portfolio Community Advisory Board (CAB). Terms of Reference, published May-October 2023. *see Annex 3.*

4. Operational procedures should:

- Define how the grantees respond to suggestions from the CAB (i.e., how decisions and recommendations are made and received).
- Detail basic operating procedures and protocols to be followed (i.e., how often and where/how the CAB will meet, meeting structure, agendas, and documenting minutes).
- Establish a point of reference during times of institutional change and leadership transitions.

Other CAB resources

Useful CAB links and resources from Unitaid funded projects and others include:

- [CHAI Optimal CAB Newsletters](#)

- On the [CHAI Homepage](#), using the [Search Function](#), type: [Community Advisory Board](#), press Enter and some 39 items are displayed featuring Unitaid and United States Government funded projects which include a CAB.
- [Know Your CAB: Community Experts Shaping the Long-Acting Technologies Pipeline](#), Treatment Action Group CAB for long acting, October 2021
- The Treatment Action Group has worked with partners to develop a number of CABs such as the [Global Tuberculosis Community Advisory Board \(TB CAB\)](#) and published a [10-year evaluation report](#) in March 2022. TAG is currently working with partners to develop [three regional CABs with Afrocab Treatment Access Partnership \(Afrocab\), APCASO \(Asia-Pacific region\), and Eurasian Community for Access to Treatment \(ECAT\)](#). [Global TB Community Advisory Board \(TB CAB\) Terms of Reference](#)
- A [Global TB Community Advisory Board](#) was formed in 2011 by TAG and other stakeholders. [Global TB CAB the terms of reference](#).
- In July 2023, TAG released An Activist’s Protocol Review Toolkits developed in consultation with members of two existing CABs — the TB CAB and the Community Research Advisors Group (CRAG) — and includes four tools designed to facilitate community participation in the development of clinical trials protocols, specifically: a protocol review companion, a protocol input questionnaire, a feedback letter template, and a trial impact assessment. These tools have proven useful for the CRAG in its role advising the Tuberculosis Trials Consortium (TBTC) and for the TB CAB in its engagement with independent investigators and research and product sponsors.
- [Musonda Simwinga, John Porter and Virginia Bond \(2018\). Who is answerable to whom? Exploring the complex relationship between researchers, community and Community Advisory Board \(CAB\) members in two research studies in Zambia.](#)
- Pancras, G., Sunguya, B.F., Sirili, N. et al. The role of community advisory boards in community-based HIV clinical trials: a qualitative study from Tanzania. BMC Med Ethics 23, 1 (2022). <https://doi.org/10.1186/s12910-021-00737-w>
- PAHO CAB/research related short videos:
 - [How can the community participate in health research?](#)
 - [Why is health research necessary?](#)
 - [Are there risks associated with participating in a clinical trial?](#)



Annexes

Annex 1: Optimal CAB

The Optimal CAB was established in 2016 to foster the engagement of members of communities and civil society groups to co-develop product adoption and roll-out strategies and to improve understanding of new treatment and regimens and generate demand.



First Optimal CAB meeting in Dakar, Senegal

In brief, the Optimal CAB supplied strategic direction and leadership in strengthening community engagement in portfolio implementation (including during Covid-19). It produced demand generation; enhanced treatment and health literacy; ensured the voices of people living with HIV were at the centre of decisions made during the implementation of Unitaids' ART Optimization Portfolio and in WHO guideline development; nurtured coherence among the portfolio grants; and supported and complemented the activities of the global HIV treatment community.

Specifically, AfroCAB (through the Optimal CAB) engaged in the following:

Built treatment literacy and demand for new products by creating publicity for new drugs and by communicating up-to-date research information clearly and concisely to communities living with HIV. AfroCAB, in partnership with CSOs and CHAI through the Optimal CAB, worked to build community literacy, awareness and demand around new, optimal treatments and to address misconceptions and resistance to uptake. In Malawi, for example, media engagement played a significant role as AfroCAB representatives relied heavily on local and national radio stations to disseminate information and to build demand for DTG and pDTG. AfroCAB fostered demand generation and understanding of ARV and AHD commodities. For example, CABs trained and engaged community leaders, national PLHIV networks, and civil society to drive the fastest transition in pediatric HIV treatment

Developed context-appropriate and language-sensitive treatment literacy tools, which became key to the demand for, and uptake of, new treatment regimens. CAB members developed a suite of information, education and communication (IEC) materials for pediatric DTG that MoH are adapting on over 10 countries. For example, in Côte d'Ivoire – under the leadership of the Programme National de Lutte contre le Sida (PNLS) and in collaboration with the Ivorian Paediatric Society – the Optimal grant supported the update of treatment literacy materials, such as fact sheets on key national guidelines for the management of HIV in children and adolescents. These materials were made publicly available through the New Product Introduction Toolkit and also by coordinating with partners such as PEPFAR for them to adopt these materials rather than duplicate effort.

Ensured that the community voices are at the centre of national and global decision-making. AfroCAB worked with policymakers to advocate for optimal treatments for people living with HIV, including for updated national guidelines and increased national budgets. Alongside the Optimal trials, AfroCAB – supported by the Optimal grant, and in collaboration with CHAI – played a decisive role in the adoption of optimal treatments in countries, including through raising community awareness and advocating to the government for the approval of new treatments. CAB members supported national policy adoption and implementation planning for pediatric DTG. AfroCAB advocated at both global and country levels for the inclusion of more tolerable, optimal products (in this case, DTG-based regimens) in WHO and country guidelines (see box below).

Women living with HIV advocating at the country and global levels for changing WHO and country guidelines around the use of DTG/TLD by women of reproductive age

In response to the neural tube defects safety signal in 2018¹, a forum of 40 women living with HIV from 18 countries engaged in dialogue to demand equitable access to optimal HIV treatments at an AfroCAB meeting in Rwanda with support from CHAI and funding from Unitaid. Subsequently, a joint position statement demanding choice and access to TLD was released. The convening also served as a model for community consultations across several focal countries (including Zimbabwe, Kenya, and Malawi).² Other examples include Malawian and Ugandan regulators consulting with community HIV groups. Few other organizations were reported to be working in this space and building community capacity in the same way.

Intensive mobilisation and advocacy campaigns were launched by community groups supported by the Optimal grant, including AfroCAB. Women living with HIV from several focal countries advocated at the country and global levels for changing WHO and country guidelines around the use of DTG/TLD by women of reproductive age. In 2019, WHO lifted the caution on the use of DTG for women of childbearing age (focusing instead on informed consent) after additional research found that the risk of NTDs was lower than previously suspected. Alongside lobbying international partners, in Kenya this resulted in a petition drafted to NASCOP and the MoH, asking for a revision of the cautionary measures barring women from accessing DTG based on more recent medical opinion. NASCOP subsequently issued an updated circular in Kenya.

CAB members participating more widely in international conferences to share their experiences, resources, and tools, and to expand advocacy for optimal treatments beyond Unitaid grants. Key examples include [Optimal CAB members' participation in the 2018 AIDS conference in Amsterdam to demand that DTG/TLD be offered to women of childbearing potential](#) and [CHAI and AfroCAB sharing the successes of community engagement at the 2022 AIDS conference](#). Other examples include:

- In June 2022, AfroCAB and CHAI convened a Community Forum to advance alignment on urgent advocacy efforts for cabotegravir long-acting injectable (CAB-LA), a long-acting prevention and treatment option. The meeting included a [dynamic, decision-making activity](#) where participants discussed and debated preferences and perspectives on long-acting products, culminating in the [CAB-LA Community-Forum Statement](#) on the urgency to accelerate access at scale to CAB-LA for people living with HIV, and in an advocacy group to focus on demand-generation and engagement with policymakers.
- AfroCAB [shared an open letter](#) with the WHO as a follow-up to a community and advocates sign-on [letter released on 3rd December 2022](#). The statement called on WHO and others to accelerate access to DRV/r in the second line (2L) of HIV treatment.
- In April 2023, AfroCAB hosted a [Community Forum: Supporting Affordable Access to Long-Acting Technologies; the Future of HIV Prevention and Treatment](#) providing the opportunity for learning, discussion, and coordinated planning to ensure the future introduction of new long-acting treatment and prevention programming is led by and cognizant of community needs.

Strengthened community engagement in product adoption to ensure smooth transition and rollout of new products. For example, by partnering with health facilities: CAB members trained mentor mothers and patient support groups to raise awareness about pediatric DTG and provide feedback channels to national programs and implementing partners. Also, monitored the roll-out of the new regimens at the facility and district levels, and informed governments of any changes in treatment outcomes. In [Malawi](#), for example, AfroCAB (through the Optimal CAB) filled a key gap in community engagement and monitored the roll-out of

¹ In 2018, the use of DTG as a first-line regimen for women of reproductive age was discouraged due to safety signals on potential neural tube defects (NTDs) in babies born to mothers exposed to DTG during the periconception period. This included safety communications and recommendations from the Southern African HIV Clinicians Society, South African Health Products Regulatory Authority (SAHPRA) and WHO. By the time WHO issued its warning, Kenya had already started administering DTG to women living with HIV. The country subsequently withdrew the use of DTG for women of reproductive age (15-49). Communities of women living with HIV in Kenya were highly concerned that they had not been consulted on this decision, which would fundamentally affect their right to choose their treatment options (regardless of their age) and their ability to make decisions regarding their reproductive lives.

² Harris EL, Blumer K, Perez Casas C, Ferris D, Amole C, Doherty M, Auton M. Accelerating access and scale-up of optimised antiretroviral therapy in low-income and middle-income countries: results of a coordinated end-to-end approach. AIDS. 2021 Dec 15;35(Suppl. 2): S165-S171.

DTG and pDTG. AfroCAB also ensured supply to health facilities through on-going communications with the MoH on uptake and stock-outs and, as a result, were seen by the government as key strategic partners in HIV response. In Côte d'Ivoire, AfroCAB contributed to strengthening community action on treatment literacy in the most disadvantaged areas (such as rural and remote areas), thus contributing to reaching underprivileged populations.

Provided training and mentorship to community representatives, CSOs, PLHIV and their carers on adherence and the side effects of the new optimal treatments. Community representatives who participated in Optimal CAB meetings shared their knowledge with CSOs, health workers and PLHIV in LMICs.

Provided key inputs to guide ART Optimization Portfolio implementation. Community organization representatives gained the skills necessary to represent communities and ensure the voices of people living with HIV were heard by projects in relation to implementation and strategic decision-making during Optimal CAB meetings.

Shared learning and best practices in engaging with communities, global-level organizations and government representatives; influenced them to pursue a similar approach. For example, in Kenya, NASCOP – influenced by the Optimal grant – has now updated the National Transition and Treatment Optimisation Workplan to ensure that community engagement is one of eight key performance areas in optimising treatment.

Adapted their approach to engaging with communities and CSOs during the pandemic. In addition, in 2020, the Optimal project partners (CHAI and AfroCAB) launched a [community consultation and webinar series](#) to inform community partners about accessing HIV care and treatment during the COVID-19 pandemic and provide a forum for people living with HIV to share their insights and experiences and identify community-based solutions and strategies to address access challenges

Created space for reflection. For examples:

- In August 2022, CHAI and Afrocab held the [annual Optimal CAB meeting](#) where CAB members from 14 African countries met, allowing Afrocab and CHAI to reflect on the impact of the CAB on both HIV treatment optimization in country and on personal growth as national HIV leaders and advocates. As participants noted, the CAB experience has instilled among members important training proficiencies and communication skills, and equipped members with critical knowledge for advocacy, allowing them to reinforce their position as key stakeholders nationally and internationally.
- [Reflections on end of Optimal grant engagements](#): The Optimal CAB has achieved remarkable success over its tenure. To ensure sustained community engagement beyond the grant, all Optimal CAB members planned and hosted engagements in each country at the end of 2022 to discuss progress achieved thus far and work that communities will take forward beyond the grant. The meetings were tailored to each country's context and celebrated CAB member and partner successes over the Optimal period. Importantly, these meetings also looked ahead at specific implementation gaps, as well as roles and responsibilities for the future.



pDTG community advocacy video

Shaping Policy & IEC Materials

CAB members supported **national policy adoption and implementation planning** for pDTG, and developed a suite of IEC materials that MOHs are **adapting in over 10 countries**

Partnering with Health Facilities

CAB members are training **mentor mothers and patient support groups** to raise awareness about pDTG and provide feedback channels to national programs and implementing partners



The introduction of pDTG has liberated my life. I give my daughter her treatment once a day and I can go to the market without worrying about her next dose.

— Caretaker from Cote d'Ivoire



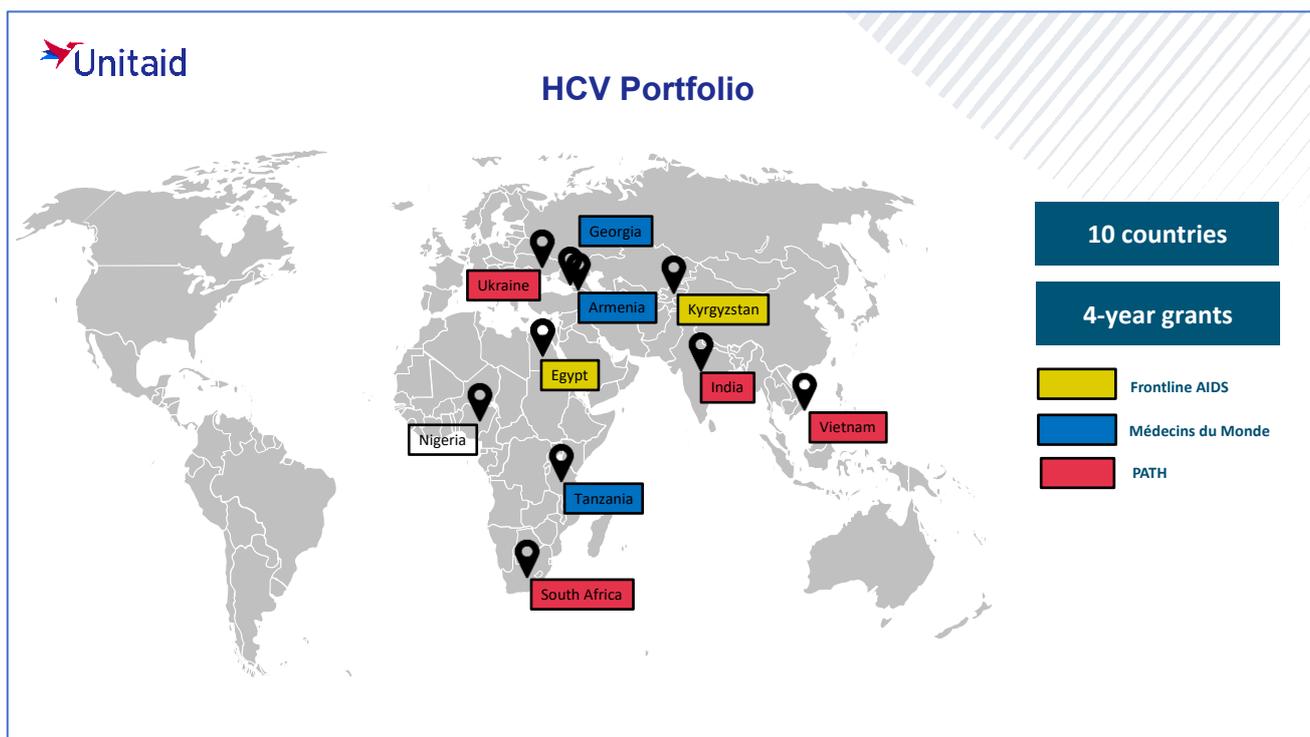
Workshop on pDTG with community leaders
— Senegal, June 2021

Driving Community Demand

CABs are training and engaging **community leaders, national PLHIV networks, and civil society** to drive the fastest transition in pediatric HIV treatment

Annex 2: Hepatitis C Portfolio Community Advisory Board

In 2023, Unitaid announced a [US\\$31 million investment in harm reduction efforts to prevent hepatitis C \(HCV\)](#) among people who inject drugs and others at high risk implemented through three complementary projects by [Frontline AIDS](#), [Médecins du Monde](#), and [PATH](#) over four years with a one year inception phase. Unitaid's funding is to facilitate the introduction of two innovative and under-used products – notably low dead-space syringes (LDSS) and long-acting depot buprenorphine (LADB); improve the models of care for HCV treatment; and demonstrate the integration of HCV prevention, testing and treatment in harm reduction services and/or prisons. The projects will also generate evidence critical to enabling the broader use of these products, including understanding user preferences, addressing high costs and increasing demand. Both products will be piloted at sites in project countries: Egypt, India, Kyrgyzstan, Nigeria, South Africa, Tanzania, Ukraine, and Vietnam with sites in Armenia and Georgia, also trialling low dead space syringes.



This first of its kind portfolio level CAB, an HCV Portfolio of Projects Community Advisory Board (CAB), was established to ensure that the voices, expertise, and the perspectives of community from all the projects inform all stages of the process and that community is engaged from the outset. As such, the purpose of the HCV Portfolio of Projects CAB is to contribute input, engagement, and participation to the ethical monitoring, implementation, and evaluation of the HCV Portfolio research projects to ensure that the lived/living experiences and feedback of people who use drugs inform the study and that the work contributes to improved access to HCV prevention. While the CAB's role is only advisory, it is expected that the advice of the CAB will be taken up or consultation held as to why not.

The CAB comprises 26 persons, including two CAB members for each of the 10 focal countries, two regional community network representatives (African Network of People who Use Drugs (AfricaNPUD) and Eurasian Network of People Who Use Drugs (ENPUD)), supported by 3 language support/capacity building mentors (one from community). Note that all CAB members are paid a sitting fee and for reading and preparation time.

In terms of CAB administration and governance, the CAB Secretariat role is currently held by Frontline AIDS with International Network of People who Use Drugs (INPUD) to take up this role in the future, while the role of CAB Chair is held by INPUD with Deputy-Chair by Coact. Community Technical Specialists support and advice is provided by INPUD and Coact. While CAB meetings are likely to be every three months for the remainder of the project now that the review of the protocols is completed, there is potential for ad hoc ones as required.



The CAB will operate in various languages reflecting the needs of participants, with translation thus far having been provided in Arabic, English, Russian and Vietnamese. Translation for the CAB comprises simultaneous translation, peer support, tech-assisted captioning, etc. This will of itself create challenges and efforts to address these will be crucial for the success of the CAB and the projects with the lessons learned informing future multi-language collaborations. For example, experience of the CAB gained to date has found that simultaneous translation works very well in online formats but is more challenging for the one meeting which was undertaken in a hybrid format, with some people meeting in-person and others online. Use of [Google Translate](#) to quickly and correctly translate comments in the chat box into other languages was easy to do and facilitated answering written questions well. One major limitation has been a lack of budget and time to translate the Master Protocol documents for review, meaning that CAB members who are not proficient in English were reliant on the support of peers to review the documents, Google Translate, or the verbal explanation provided through professional translation services at the CAB meetings.

In the first six months from May-October 2023, the HCV CAB Terms of Reference (ToR) was developed and finalized (see *Annex 3*), the nomination process for CAB members was undertaken and completed, the Master Research Protocol Review Framework was developed, and four CAB meetings were organized and held including: 1. Project Orientation and Protocol Review Capacity Building, 2. Low Dead-Space Syringes/Needles (LDSS/N) Master Research Protocol Review, 3. Long-Acting Depo Buprenorphine (LADB) Master Research Protocol Review, and 4. HCV Models of Care (MoC) Research Protocol Reviews (Consortium-based CABs).

Such meetings have resulted in substantive changes due to CAB input, for example, key changes to the LADB protocols include:

- Abstinence was removed as an outcome with changes in drug use (i.e., frequency of injecting of non-medical opioids in the last month) used as the measure.
- Use of urine testing was raised as stigmatising, expensive, ineffective, and likely to make people drop out of the study. As a result, urine testing was removed from the protocol though some countries still require it.
- Choice of participants to take part or not, so it was agreed that it is extremely important to communicate this to participants in this study.
- A lack of knowledge and information on LADB so it was agreed to develop community-led information, client resources, tools, and sessions to build knowledge and understanding among communities/ participants.
- Flexible, individualised treatment and dosing will be included in the LADB clinical treatment guidelines and explored in the qualitative research.

- The importance of Community Researchers, who speak local language so that focus group discussions (FGDs) and key informant interviews (KIIs) are more effective (i.e., people more likely to talk) was agreed and are included in qualitative research.
- Timeline of the study, including the length of access during study and ongoing access to LADB was raised.

Annex 3: Unitaid HCV Portfolio Community Advisory Board Terms of Reference (ToR)

Background

The Unitaid HCV Portfolio Projects (hereafter referred to as the HCV Portfolio) are three Unitaid-funded research consortia testing the feasibility, acceptability, and effectiveness of innovative harm reduction tools to prevent hepatitis C virus infection (HCV) among people who inject drugs (PWID) and other high-risk populations. The HCV Portfolio includes research sites across ten countries, led by the following organizations: Frontline AIDS: *Innovate, Involve, Inspire: Preventing Hepatitis C Through Community-Led Harm Reduction (HEPCIII)*, Médecins du Monde: *Catalyse uptake of Under-utilized Tools & Treatment Simplification for Hep C (CUTTS HepC)* and PATH: *HCV Combination Prevention in PWID and Prisoners Project (HEPC3P)*. The HCV Portfolio aims to generate evidence critical to enabling the broader use of low dead space syringes and needles (LDSS/N) and long-acting depot buprenorphine (LADB), including understanding user preferences, addressing cost effectiveness, increasing demand, and demonstrating effective delivery.

The Unitaid Strategy 2023-2027 outlines an increased commitment to building community engagement and inclusive partnerships across Unitaid's activities as part of a greater focus on equity. In line with this commitment, the three consortia (*HEPCIII, CUTTS HepC, HEPC3P*) agreed at the HCV Portfolio Research Framework Development Meeting held in Geneva on 22-24 March 2023 to establish a cross-cutting Community Advisory Board (CAB). All three consortia must meet Unitaid requirements on engaging with civil society and communities across all stages: from conceptualisation to monitoring, evaluation, and learning.

Further, at the HCV Portfolio Research Framework Development Meeting, the HCV Portfolio agreed to submit, for WHO ethics review, a "Master Protocol" for each of the two research interventions, LDSS/N and LADB. This Master Protocol approach allows for the standardization of interventions across the HCV Portfolio research sites. The three consortia are responsible for submitting, as appropriate, a LDSS/N and LADB Master Protocol with a country-specific addendum for their respective research sites.

Community-led Technical Partners

The International Network of People who Use Drugs (INPUD) and Coact Technical Support Limited (Coact) are community-led technical experts. Both organizations have funded roles supporting one of the HCV consortia – INPUD / MDM and Coact / Frontline AIDS. INPUD and Coact will support the work of the CAB and technically support the work of the country and other community-led members as they review the Master Protocols and the unfolding work of the HCV Consortia. INPUD is a global network of people who use and have used drugs. The organization's key role is to support people who use drugs to access and participate in international policy processes. The Executive Director of INPUD will lead on chairing the CAB to support meaningful community consultation.

CAB Purpose and Role

The purpose of the Unitaid HCV Portfolio CAB is to contribute input, engagement, and participation to the ethical monitoring, implementation, and evaluation of the HCV Portfolio research projects to ensure that the lived experiences and feedback of people who use drugs (PWUD) inform the study and that the work contributes to improved access to HCV prevention. The CAB will work with the project principal investigators (PIs) and respective project teams to:

- Advise on study design, protocols, enrolment, recruitment and community education to ensure community voices, concerns and impact are considered.
- Act as ambassadors for the project by sharing information and progress among the regional- and country-community-led networks of people using drugs and the global community.

Specific activities include (but will not be limited to):

- Providing review and feedback on the Long-Acting Depot Buprenorphine (LADB) and Low Dead-Space Syringes/Needles (LDSS/N) research protocols, study design and research tools.
- Monitoring study implementation, recommending community-led monitoring approaches and providing advice on implementation challenges.

- Fostering community education, engagement, and knowledge exchange.
- Recommending communication and information dissemination strategies.
- Ensuring efficient use of community-led technical support resources and avoiding duplication.
- Supporting and advising on demand generation.
- Acting as a focal point concerning risk management so country community-led partners have a clear route to share lessons, highlight concerns, troubleshoot, and identify effective strategies.
- Act as representatives to national or country-level steering committees to facilitate strong linkages and enhance community participation at the national/country level.

The fundamental principle underpinning the operation of the CAB will be the promotion and protection of human rights and equity concerning people who use drugs in all aspects of the HCV Portfolio.

In the Inception Phase (January to December 2023), the CAB will review the LDSS/N and LADB Master Protocols and advise the Master Protocol Writing Groups. The writing teams are expected to formally receive, consider, and respond to the advice provided by the CAB. If advice is not adopted, the writing teams will share their reasoning with the CAB to support informed dialogue and demonstrate their meaningful engagement with the community advice.

Governance

The CAB will advise and represent the HCV Consortia project leads and PIs during relevant HCV Portfolio coordination meetings. The CAB will include a minimum of 15 and a maximum of 20 members appointed by the HCV Consortia. The chair is held by the International Network of People who Use Drugs (INPUD) (a member of the CUTTS HepC consortium). Coact, a member of the HepCIII consortium, will hold the vice-chair. Members will reflect, to the greatest extent possible, the diversity of project sites/settings and strive for gender balance. The CAB may be expanded occasionally, including establishing time-limited subgroups to address specific issues or topics as required.

Membership selection criteria and duration of the appointment

Members will be suggested by each participating consortium (HEPCIII, CUTTS HepC and HEPC3P) based on nominations from country partners/drug use organizations and appointed to the CAB with consensus by the CAB Chair and Vice-chair. Members should represent the project focal countries and international and regional drug user groups.

Criteria include:

- Reflect the diversity of communities of people who use drugs and incorporate a range of critical intersections, e.g., gender identity, sexual orientation, age, race, cultural background, abilities, and socio-economic status.
- Include a geographic spread across countries and regions and, to the greatest extent possible, be representative of the focal countries.

Membership will be for the duration of the Unitaid HCV Portfolio consortia projects (through December 2026). If replacement members are needed, the CAB secretariat will work with drug user organizations in the country to nominate alternate members. The CAB will meet quarterly in the first year via a secure online platform. While there is the potential for in-person or hybrid meetings of the CAB, such gatherings would require additional resources. In-person meetings could be planned around critical events or conferences.

CAB Member Responsibilities

The CAB is requested to contribute to the ethical monitoring, quality, and roll-out of the HCV Consortia research projects across study sites. Members commit to the following:

- Participate in all meetings, with apologies sent informing in advance when attendance is not possible.
- Declare conflicts of interest when joining the CAB and report any changes to the conflict-of-interest information when they arise.

- Notify the CAB chair as soon as practical if any matter arises that may affect the development and success of the HCV Portfolio project work.
- Protect confidential and sensitive information or documents associated with the HCV Consortia work.
- Decline any incentives, benefits or remuneration from external parties for their participation or because of their membership in the CAB.
- Actively participate in discussions and meetings and commit to an open, honest, and participatory engagement.
- Support and foster linkages between project sites and activities as appropriate.
- Maintain focus on the agreed scope, outcomes, and benefits of the HCV Portfolio work and strive for timely actions and decisions.
- Act as HCV Consortia ambassadors and bring external opportunities and challenges that impact the work to the CAB for discussion.

A quorum will consist of 75 per cent of the Advisory Board. Recommendations will be made by consensus, and if not possible, the CAB Chair and Vice-Chair will make the final decision.

Training & Technical Support for CAB Members

Training and capacity building will be provided for CAB members upon appointment to ensure all members have the necessary technical knowledge, skills and understanding to participate in discussions on relevant policy, research, and project implementation matters as required. Training will ensure members understand technical, programmatic and operational issues (including information about new or innovative medications, technologies, commodities, etc.) to fully support their ability to participate in deliberations. External advocates and other relevant experts may be invited to present during meetings to provide the range of perspectives and information required.

Technical Support for CAB Members

The CAB will provide a forum for country community-led experts to share their expertise. Up to two representatives from a country may be selected to help ensure that community-led members with more robust research or project management expertise can support those with strong living experiences. Two to three additional community-led experts with strong academic backgrounds would be included from other LMICs to ensure the full review of the two Master Protocols and accompanying research tools supporting community-led members.

Language, Translation/Interpretation

Language and translation/interpretation will be mainly managed through informal, practical measures, including peer support about meeting papers and reports and during CAB meetings. Due to limited resourcing for professional document translation, informal, free-of-charge online platforms will be used to translate documentation as required for CAB meetings. Emerging translation and interpretation will be a matter for ongoing discussion and review once the CAB members have been appointed, with the potential to discuss resourcing needs for professional translation and interpretation with the three consortia and Unitaid as required.

Simultaneous translation into Russian will be required to support the meaningful review of the Master Protocols and supporting resources by community-led leaders from countries such as Armenia, Georgia, Kyrgyzstan, and Ukraine. Coact has a Russian-speaking technical consultant who can support break-out calls and day-to-day development work concerning the CAB with Russian-speaking partners. Emerging translation and interpretation will be a matter for ongoing discussion and review once the CAB members have been appointed, with the potential to discuss resourcing needs for professional translation and interpretation with the three consortia and Unitaid as required. Document translation will be limited during the consultation and development period.

CAB Secretariat

The CAB will not have legal status, so it cannot have responsibility for a budget, enter into contracts or legal agreements, or be held legally liable.

Frontline AIDS and later INPUD will act as the secretary for the CAB and support the CAB Chair and Vice-chair. As the secretariat, Frontline AIDS commits to an ongoing collaborative relationship with community members, each of the HCV Consortia projects and their country partners.

Secretariat activities include:

- Serve as the point of contact for the HCV Portfolio partners
- Provide administrative support for the proper functioning of the CAB, i.e., distribute relevant materials to and from the CAB, including agenda, meeting minutes, and relevant documents and materials.
- Support logistical arrangements for members to attend meetings (virtually) or other activities.
- Liaise with the HCV Consortia project teams as needed on behalf of the CAB.
- Compile reports on the activities of the CAB for the HCV Consortia and, where appropriate, for broader dissemination.

CAB Budget

Frontline AIDS and later INPUD will manage the CAB budget and related operating costs.

CAB member remuneration

All CAB members will be paid an honorarium to cover the time spent attending meetings and a reasonable reading and preparation time. A standard honoraria rate, nominal payments for non-staff in recognition of contribution and time invested, will be paid for preparing for, attending, and participating in quarterly CAB meetings. Frontline AIDS will make payments as the CAB secretariat. Fixed half-day participant rates will be recommended by INPUD and finalised in consultation with HCV Portfolio members.

Any additional payments to CAB members for undertaking work in their role (other than the regular CAB meeting honoraria) must be negotiated and approved in writing by the CAB secretariat before the time it worked and before payment.

All reasonable out-of-pocket expenses associated with acting as a CAB member will be covered, including per diems and travel costs associated with attending in-person CAB meetings. Members must get prior written approval from the CAB secretariat for all out-of-pocket expenses before they are incurred.

Amendment, Modification or Variation

These Terms of Reference may be amended, varied, or modified after consultation and agreement by the CAB members (as relevant).

Version	Date Approved

Annex 4. LSHTM TRANSFORM project Community Advisory Board – Terms of Reference

INTRODUCTION

The WOMAN Trials have a simple goal. To ensure a safe childbirth for all women everywhere. These global trials are producing the evidence needed to stop women dying in childbirth. Heavy bleeding after childbirth, called a postpartum haemorrhage or PPH, is the main cause of maternal death, killing tens of thousands of mothers every year. The WOMAN trials are looking at the effect of the drug tranexamic acid (TXA) on bleeding and the best ways to give it.

The TRANSFORM project is generating evidence and demand, raising awareness, and addressing supply issues to ensure tranexamic acid access for all mothers with bleeding after childbirth. The I'M WOMAN trial, part of the TRANSFORM project, is looking at easier and more accessible ways to give TXA – intramuscularly, rather than intravenously – with the aim of expanding access to timely TXA treatment.

If TXA could be given intramuscularly, women giving birth outside of hospital would have access to this lifesaving drug and healthcare workers would be able to treat women faster. This is crucial when a woman can bleed to death in a matter of minutes. The trial will start recruiting 30,000 women in 2023.

SCOPE

The purpose of this document is to describe the roles and responsibilities of the Community Advisory Board (CAB) for the TRANSFORM project, including the role of the CAB, member responsibilities, timing of meetings, methods of providing information, frequency and format of meetings, and relationships with other committees.

ROLE OF THE CAB

The role of the Community Advisory Board (CAB) is to:

1. advocate for and raise awareness about tranexamic acid and postpartum haemorrhage
2. represent the interests of women and amplify women's voices
3. build a network of key members and stakeholders
4. provide views on project materials (e.g., protocol summary) and trial results
5. support communications and engagement activities

The role of the CAB is advisory only, and advice is not binding.

RESPONSIBILITIES

Specific responsibilities will vary by member, as each member may bring a different set of skills, knowledge, and experience to the board. Activities may include but are not limited to:

- Attending CAB meetings to review and comment on the progress of the project
- Acting as ambassadors for the project by communicating the vision, objectives, and progress to their community
- Generating ideas on how the project can best engage with civil society and community groups to maximise the benefits of tranexamic acid and generate demand
- Making inputs into the project materials as requested, for example through review of education materials or communication plans.

MEETINGS

The CAB should meet approximately twice a year, but any member can call a meeting at any time. Meetings can be on a group or individual basis. Meetings may be regional or topic specific. Meetings will be organized by the Project Lead, Senior Project Administrator or Communications Manager, who should ensure papers are prepared and circulated in advance, where needed. An accurate minute should be prepared by the organizer or other nominated attendee from the London team. Routine business will be conducted by email. Effort will be made to ensure that members attend their meetings as planned.

MEMBERSHIP

The CAB will constitute individuals with relevant experience or knowledge who may be co-opted as appropriate, with representation from project countries and worldwide. Members will range from lay representatives to skilled professionals to ensure a range of views. The CAB will be chaired by the Project Lead for the I'M WOMAN trial. A list of current members will be circulated prior to each meeting.

RELATIONSHIP TO OTHER COMMITTEES

The CAB will provide feedback to the Project Management Group (PMG) and PPH Programme Advisory Committee (PAC) via the Project Lead or Chief Investigator. Relevant issues will be fed back to the Trial Steering Committee (TSC). Members of the CAB may also sit on other committees, as appropriate.

Synergies with other members of the Unitaid PPH portfolio and links to other CABs, advisory groups and community and civil society engagement (CCSE) initiatives will be leveraged when appropriate. If the TRANSFORM CAB is aware of other CCSE initiatives in the PPH portfolio, we will look for opportunities for collaboration and coordination.

CONFIDENTIALITY

Discussions are intended to be as informal as possible, therefore normally, CAB meetings will be held under Chatham House rule. In circumstances where confidential information such as trial results are to be shared, members of the CAB will be notified and asked to sign a confidentiality agreement prior to the meeting.

Annex 5- D²EFT Community Advisory Board Terms of Reference



1. Introduction

[Insert a short description of study including number of participating countries across number of regions]

2. Role of the community advisory board

The establishment of the Community Advisory Board (CAB) will serve to foster engagement with civil society groups. The role of the CAB will be to provide strategic direction and leadership to strengthen community engagement in project implementation and to foster awareness and participation. CAB members will represent the voices of trial participants from their various geographic areas, collating community experience and views on all aspects of trial conduct and identifying problems and/or barriers to enrolment within the project. CAB representatives become the voice and the link between the CAB and the project team via the Protocol Steering Committee (PSC). Efforts will be made to ensure that CABs reflect the local demographics of the HIV epidemic.

The CAB will work with the project team to represent the interests of the global HIV community within the project by:

- Communicating the relevant needs, views and experiences of the community to the project team;
- Ensuring the project meets local needs and contributes to improved treatment outcomes for people living with HIV;
- Raising issues that could adversely or favourably affect successful recruitment and implementation of the project;
- Staying abreast of project progress through planned CAB teleconferences;
- Monitoring progress and ensuring that project outcomes are shared with the global HIV community.

3. Responsibilities of the community advisory board

The CAB is requested to contribute to the recruitment, ethical monitoring, quality, and roll-out of the D²EFT study by carrying out certain activities, including but not limited to:

- Participating in planned CAB teleconferences to review and comment on the progress of the project and recruitment;
- Acting as ambassadors for the project through communicating the project objectives and progress to the global community;
- Generating ideas on how the project can best engage with civil society and community groups;
- Advising the project team on key project activities, including potential risks and how to minimize them;
- Monitoring local media coverage and social media activity for issues that may be relevant to the project. They may be requested to provide local media reports to the project team 1-2 times a year, drawing

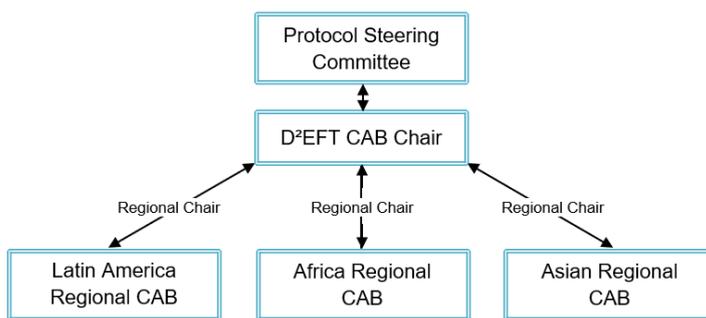
attention to key areas of opportunity or concern. This may involve translating brief summaries of media articles from local languages into English.

Key considerations/guiding principles for the CAB will include:

- The promotion and protection of human rights and equity in all aspects of the project;
- Ensuring the CAB takes an independent, evidence based, and non-biased stand on issues pertaining to the project.

4. Governance

There will be 3-5 regional CABs set up to represent the geographic regions participating in the project. A single representative from each regional CAB will be nominated to hold the position of Regional Chair (i.e. 1 Regional Chair per regional CAB). The flow of information between the PSC and each regional CAB will be via the Regional Chairs and the D²EFT CAB Chair. The appointed D²EFT CAB Chair will hold the position of CAB representative on the PSC. For all Chair positions, a Deputy Chair should also be appointed to take on the Chair’s duties if they are unavailable.



CAB communication diagram (demonstrated with 3 regional CABs)

Face-to-face PSC meetings are held 1-2 times a year. In addition, PSC teleconferences are conducted as needed. The D²EFT CAB Chair is expected to attend these meetings and join the calls.

The Regional Chair from each regional CAB will organize teleconferences 2-4 times per annum during the recruitment period and at least annually thereafter until acceptance of the primary manuscript. The CAB will decide by consensus if there is a further requirement for meetings after this time. If a vote is to occur, every CAB member gets one vote. A back-up member can be nominated in each country to fill-in should the primary member be unavailable.

Terms of Membership/Role of Members

- CAB members will be HIV community representatives (e.g., community activists, HIV study participants). At least one third of CAB members should be female.
- Each regional CAB will have 1 primary member per participating country (e.g., the African Regional CAB will have 5 primary members, 1 from South Africa, 1 from Mali, 1 from Guinea, 1 from Nigeria and 1 from Zimbabwe). A back-up may be nominated to stand in should the primary member be

unavailable. Coordinating Centres will be asked to liaise with sites to determine the best representative(s) for their country.

- Each regional CAB will elect a Regional Chair to feedback to the CAB Chair.
- A Conflict-of-Interest disclosure form is required to be completed by all members on joining the D²EFT CAB. This must be updated any time there are changes to the reported information over the course of the study. Suspected conflicts should be brought before the CAB with a report provided to the Project Team.
- Members will be expected to decline any incentives, benefits or remuneration from external parties for their participation or because of their participation in CAB activities.
- Attendance on all calls is requested, with apologies sent when this is not possible. In this circumstance, the back-up member should be requested to participate.
- CAB members will be expected to actively contribute to discussions.
- CAB members will be expected to take responsibility for relevant action items.
- The term for membership will be for the duration of the project.

Coordination and administrative arrangements for the D²EFT CABs

The Regional Chair from each regional CAB will carry out the administrative tasks listed below:

- Providing administrative support for the proper functioning of the CAB in line with its purpose
- Distributing relevant materials to and from the CAB including distribution of the agenda and minutes prior to and after the CAB meetings
- To collect, collate and disseminate documents for input from the CAB
- To liaise with members of the CAB as needed.

In addition, the D²EFT CAB chair will have the following responsibilities:

- Be the point of contact with the project team
- To liaise with the project team as needed
- To compile reports on the activities of the CAB for the project team and, where appropriate, for wider circulation.

Budget: The CAB will not have legal status so cannot have responsibility for a budget, enter into contracts or legal agreements, or be held legally liable. The Kirby Institute will support the cost of teleconferences. Face-to-face PSC meetings are held in conjunction with other major international HIV meetings (e.g. CROI, World AIDS, IAS). Funding is not provided for travel to PSC meetings. If the CAB Chair will not be attending the associated international meeting it is hoped the Deputy Chair will be in attendance and can join the PSC meeting in place of the Chair.

5. Communication

Project updates (progress and results) will be communicated to the CAB Chair by the Project Team. The CAB Chair will share this information with the regional Chairs who, in turn, will disseminate it to their members.

6. Membership

CAB Member Name	Country	Organization
Region - Latin America		
Region – Asia		
Region – Africa		

7. Payments

CABs will receive compensation for their participation in conference calls, email discussions, feedback from their community and other activities as described in this Terms of Reference.

Compensation will be provided per country (total of 14):

- Each CAB representative position (11) will receive up to US\$X per year for 3 consecutive years beginning in 2019.
- Each Regional CAB chair position from Africa, Asia and Latin America (3) will receive up to US\$X per year for 3 consecutive years beginning in 2019.
- The CAB Chair will receive an additional annual payment of up to US\$X for 3 consecutive years beginning in 2019.

The payment will be pro rata based on participation in the CAB activities noted above. Payment will be made by the Sponsor to the institution (site coordinating centre/SCC or site) in support of these CAB activities. To accommodate diverse community engagement models used at D²EFT SCCs/sites globally, distribution of CAB funds will be at the discretion of the SCC/site.

CAB payment will be included with the SCC or site payment annually, on receipt of a brief report outlining the CAB activities undertaken in the previous 12 months which align with these terms of reference.

Note: CAB members were required to sign a confidentiality agreement before they began participating in CAB activities.