



# Communities as Actors in the Research and Development Process

By Joelle Dountio Ofimboudem  
and Sara Helena Gaspar

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**TAG**  
Treatment Action Group

One of the lessons learned from the COVID-19 pandemic is that there are undeniable benefits of engaging communities as a stakeholder — alongside researchers, drug manufacturers, health care providers, policymakers, drug regulators, and other public health actors — in the research and development of pharmaceuticals, biologics, and vaccines.

Community engagement involves a process of developing relationships that enables these stakeholders to work together to address health-related issues and promote well-being to achieve positive health impact and outcomes.<sup>1</sup>

## The Value of Community Engagement

Engaging communities in promoting health and well-being by providing a platform for engagement during research and development enables and facilitates changes in behavior, environments, policies, programs, and practices necessary for public health within communities.<sup>2</sup> While the depth and level of community engagement and involvement varies from community to community across the world, the benefits are similar across the board. Namely, improvement in the sustainability, efficiency, and resilience of national health systems by meeting the financial needs of health programs and services, and supporting the initiatives of local communities. Community engagement also provides an excellent opportunity for health and research and development education and skills and competencies building; promotes community involvement in public health programs;<sup>3</sup> engenders trust in public health approaches; and provides a forum for community members to share their concerns, values, and preferences and pose questions to researchers and other public health actors. When research and development moves into the clinical trials phase, community members play a crucial role by participating in and supporting trials.

## Nothing About Us Without Us

The phrase “nothing about us without us” was coined by South Africans who were rendered permanently disabled as a result of police brutality during apartheid as they mobilized to demand that their rights and voices be taken into account during the decades-long liberation struggle to end apartheid.<sup>4</sup> It succinctly summarizes the need to involve and engage community members in the research and development process to ensure the uptake of newly developed medical products.

“Nothing about us without us” summarizes the refusal of communities to be spoken about by policymakers, researchers, and other actors while their real needs and demands remain silenced. Communities demand to be effectively included in policymaking, research and development, and every other process that will affect them. Their lived experiences provide a unique perspective into their realities, and communities demand these experiences be recognized, valued, and taken into account at all stages. Communities are not side characters, they are and should be at the center of political and scientific processes that affect them.

*Given the increased global internet connectivity and social media access, ensuring that community questions are posed to and addressed by the right people is key to building trust in the research and development process and avoiding the spread of false and misleading information, which in turn, is key to ensuring the uptake of new medical products.*

## Community Engagement Within the Longevity Project

In 2020, thanks to a [Unitaid](#) grant, University of Liverpool (UoL) started the [Longevity project](#) to develop revolutionary long-acting injectable medicines for the prevention of tuberculosis (TB) and malaria and a single-injection cure for the hepatitis C virus (HCV). These three new long-acting injectable medicines will be deployed in low- and middle-income countries (LMICs) where approximately 300 million people live with these diseases, resulting in 2 million deaths each year. Long-acting medicines have the potential to significantly reduce the burden of these diseases and contribute to their eradication.

As a member of the Longevity consortium, Treatment Action Group (TAG) coordinates community engagement and develops treatment literacy materials about long-acting therapies and access to health care for these three diseases. In a bid to ensure meaningful community engagement throughout the research and development process, TAG, in partnership with [Afrocab Treatment Access Partnership](#), created the long-acting technologies (LAT) community advisory board (CAB) in 2021 to provide a platform for engagement between community members from various countries and the Longevity consortium partners; namely, University of Liverpool, Tandem Nano Ltd., the Medicines Patent Pool (MPP), the Clinton Health Access Initiative (CHAI), Johns Hopkins University (JHU), and the University of Nebraska Medical Center (UNMC).

While the consortium members are developing these long-acting formulations and doing cost of goods analyses, the LAT CAB is engaging with them on a regular basis, posing questions and raising concerns regarding the formulations, ensuring access, and providing

unique perspectives based on their lived experiences and the experiences of their community members. To expand access to these long-acting technologies once they are available, the LAT CAB will contribute to generating interest and demand by priming health programs ahead of their development, preparing their communities and policymakers, and advising on outreach and rollout.

In addition to the Longevity consortium members, the LAT CAB has also been engaging with access to medicines experts and experts from key multilateral and global health institutions that shape and ensure access to health technologies in LMICs. This has enabled CAB members to learn about LATs, the three diseases covered under the project, enablers and barriers to access to health technologies in LMICs, and strategies for engaging policymakers. CAB members have also amplified community demands for equitable access to these health technologies once they are developed and commercialized.

## Extracts of exchanges between the LAT CAB, Longevity consortium members and other global health experts

**QUESTION 1:** Prior to the Longevity project, had UoL ever developed LATs? If yes, did any get to clinical trial stages?

**ANSWER:** Prior to the Longevity project, UoL reformulated efavirenz and lopinavir/ritonavir into oral formulations with lower daily dose requirements. However, when this reformulation work was completed (after seven years) dolutegravir, a better antiretroviral therapy (ART), was developed and became the preferred first line regimen. Dolutegravir has increased potency, a favorable side effect profile, and a high barrier to the development of virologic resistance.

**QUESTION 2:** What stage are each of the long-acting therapies being developed under the Longevity project at?

**ANSWER:** All three are at the preclinical development stage. With respect to HCV, excellent progress has been made. The long-acting formulation of both Glecaprevir (G) and Pibrentasvir (P) are able to achieve sustained plasma concentration for 8-12 weeks, and we are still working on the ratios of each of the drugs. With respect to TB, we have also made great progress as extended exposure to rifapentine in small animals has shown an efficacy comparable to 1HP in preclinical models.

With respect to malaria, great progress was made proving that mosquitoes cannot transmit malaria resistant strains to other people, and our formulation showed considerable efficacy in rodents, but the malaria portion of the project will not be continued due to concerns over the use of a single drug rather than a combination.

**QUESTION 3:** SOF/DAC combination is the direct acting antiviral (DAA) available in most of our countries because it is the cheapest. G/P, the preferred longevity HCV cure being developed into a long-acting formulation, is super expensive and neither registered nor available in most of our countries. Would the reference price to determine the affordability of long-acting G/P be the price of G/P or the price of SOF/DAC?

**ANSWER:** Based on our preliminary cost of goods analysis, it is expected that the price of the long-acting G/P formulation will be comparable to the price of SOF/DAC or perhaps even lower.

**QUESTION 4:** What is the expected real difference and added value of long-acting HCV and TB therapies currently being developed under the Longevity project?

**ANSWER:** If the HCV and TB formulations currently being reformulated into long-acting versions prove successful, people with HCV could be cured with a single shot/injection of G/P instead of having to take tablets/pills for 8-12 weeks; people with latent tuberculosis infection would simply have to take a small series of shots/injections of rifapentine with or without isoniazid to prevent the progression of latent TB to TB disease instead of having to take the pill/tables for up to six months. In both scenarios, this would greatly improve care as people could be treated as soon as they are diagnosed, thus averting loss to follow-up and avoiding pill fatigue. This will also provide treatment discretion, which will in turn prevent stigma.

**QUESTION 5:** Does UoL have the capacity to produce LATs at scale? If not, what are the requirements for manufacturers who might want to manufacture these LATs in future?

**ANSWER:** UoL is an academic institution and does not have the capacity to produce LATs at scale. We would collaborate with a development partner — a generic manufacturer — for that. We are working to reduce the manufacturing hurdles for generic manufacturers as much as possible. For example, we are making solid forms of the medicines that can be dispersed at the point of injection so that issues such as cold chain storage are removed during manufacture and distribution. We have already started working with contract development and manufacturing organizations to ensure it is as easy as possible for generic manufacturers to reproduce the formulations at scale.

**QUESTION 6:** What kind of manufacturing capacities would generic manufacturers need to manufacture the long-acting treatments, and what can be done to build LATs capacity among manufacturers in LMICs to ensure these products are actually available for these markets once they are developed?

**ANSWER:** Based on our experience, some generic manufacturers, including in LMICs, are well equipped to manufacture such products. Further discussions on manufacturing capabilities can be conducted once the infrastructure requirement (in terms of equipment and facilities) for the technology is finalized. The MPP has a transparent Expression of Interest (EoI) process involving open calls for generic developers all over the world to express their interest in manufacturing generic versions of medicines. The EoI questions thoroughly assess the manufacturers on several aspects including (but not limited to) their infrastructure, manufacturing capability, available capacity, regulatory approvals for manufacturing plants, regulatory capability of filing, experience developing similar products, market presence in the designated therapeutic area, etc.

**QUESTION 7:** Does the MPP-Tandem Nano Ltd. voluntary license cover all the intellectual property relating to the LATs being developed under the Longevity project?

**ANSWER:** For the malaria and tuberculosis compounds used within the Longevity project, there are no active patents. All the intellectual property relating to the long-acting formulations (owned by Tandem Nano Ltd.) for the three products under development has been licensed to the MPP. However, AbbVie has patents on G/P compounds.

**QUESTION 8:** What is a “grant-back clause” in technology licensing? How will this apply in a scenario where a G/P long-acting injectable and/or a microarray patch is developed under the Longevity project based on the Tandem Nano Ltd. voluntary license?

**ANSWER:** A grant-back clause is a provision in a technology licensing agreement that obligates a licensee to license any improvements made to a licensed technology back to the original technology licensor. MPP license agreements typically contain a non-exclusive, royalty-free grant-back license from the licensee to the licensor. The Tandem Nano Ltd. license to MPP states that both development and commercialization partners are obligated to license back to the MPP and Tandem Nano Ltd. any improvements to the technology licensed to them. The G/P voluntary license agreement between the MPP and AbbVie also contains a grant-back clause, but the Tandem Nano Ltd. technology will not be implicated because the latter is not a G/P licensee.

**QUESTION 9:** Given that G/P is still patent protected, does intellectual property pose any barrier to the development of the long-acting formulation? If yes, how will this be resolved?

**ANSWER:** It depends on the national legal system. Generally, a “research exemption,” also known as “Bolar provision,” allows for research and development but not for commercialization.

## **QUESTION 10:**

**How did it happen that India was named as a “manufacture only” country in the MPP-AbbVie G/P voluntary license? Also, more than four years after the G/P voluntary license, why has no generic manufacturer developed and marketed generic G/P?**

**ANSWER:** The MPP-AbbVie license for G/P covers 96 countries where licensees will be able to supply the generic version of the product. The geographical scope of voluntary licenses depend on outcomes of negotiations with innovators and vary from license to license. MPP always strives for a maximum number of LMICs to be included in the license agreements. In some MPP licenses, manufacturing can happen in a number of territories outside the license territory (including in some cases in high-income countries). In the case of this license, manufacturing can take place in India in addition to any country in the license territory. As with all MPP licenses, we are regularly exploring opportunities to expand the scope of the license to include more LMICs in the territory.

MPP signed G/P sublicense agreements with four generic manufacturers in two rounds (2019 and 2021). According to MPP license standards, generic manufacturers are obliged to get World Health Organization (WHO) prequalification (PQ) approval, or approval of a stringent regulatory authority (SRA) as defined by the WHO, to ensure the quality of all the manufactured products. WHO included G/P in the EoI of the WHO PQ program in October 2022, finally providing a regulatory pathway for the quality assurance of G/P being developed by licensees. The complexity of G/P development process has added to the overall manufacturing timelines.

Demand for viral hepatitis therapies remains low despite affordable quality-assured hepatitis B and C treatments being available in LMICs through voluntary licenses. For example, the existing licenses from MPP and Gilead enable the availability and affordability of SOF/DAC combinations from MPP and other generic combinations from Gilead. Yet, only a few LMICs procured the products in sufficient volumes to address the needs in these countries. As a result of the low demand, and given the complexities involved, it has likely been challenging for generic manufacturers to prioritize the development of generic G/P. Inclusion of India in the license territory could contribute to improving the demand outlook for this product.



**QUESTION 11:** We have seen situations where countries that have not granted patents are included in MPP voluntary licenses. What is the rationale for this?

**ANSWER:** The rationale is, first, to increase visibility on the potential market where generic manufacturers are certain they can supply the product. Second, while there may not be patents in the country of sale, there are often patents in the country of manufacture. Therefore a manufacturer based in a country where the product is patented would need to have certainty on which market it may supply the patented product. Third, we want to ensure legal certainty for various countries. If the countries with no patents are excluded, questions might arise as to why the country is not included in the license territory. We think it is better to include countries where the medicines have not been patented than to exclude them. MPP avoids the situation where the royalties (if any under the license) are payable for countries without granted patents.

**QUESTION 12:** What is the difference between intramuscular and under the skin injections?

**ANSWER:** Intramuscular injections are administered in the muscle using slightly longer needles. In addition, higher volumes of drugs can be administered intramuscularly. Cabenuva, the HIV long-acting injectable treatment taken every two months, is administered intramuscularly.

Subcutaneous injections are administered under the skin and require slightly shorter needles. Only smaller drug volumes can be administered subcutaneously.

Injections administered through both modes can form a depot and are very well absorbed in the body.

**QUESTION 13:**

**In your work globally and in countries, what do you see as the key barriers to access to health technologies and other health care services?**

**ANSWER:** There is a list of barriers and addressing them must start with political will and a strong civil society voice demanding access. Once health advocates and/or governments have defined a health priority and are able to push through to demand for funding, access can be secured.

**QUESTION 14: Why are most MPP licenses not as broad and “almost perfect” as the Tandem Nano Ltd. license?**

**ANSWER:** First, in the case of Tandem Nano Ltd., the product is being developed with funding from Unitaid, which provides significant leverage in the licensing negotiations. Second, large pharmaceutical companies, which are often the licensors for MPP’s other licenses, operate within established markets and are often reluctant to include countries where they currently have commercial activities. This is very different in the case of a smaller organization without a global presence.

## Conclusion

Although usually the last item on research and development meeting agendas, community engagement is an invaluable component of the research and development process. The contributions community members make to health promotion and scientific research needs to be recognized, valued, and supported by national health programs, global health actors, and corporations involved in research and development.

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<sup>1</sup> World Health Organization. Community Engagement: A health promotion guide for universal health coverage in the hands of the people; 2020. <https://iris.who.int/bitstream/handle/10665/334379/9789240010529-eng.pdf?sequence=1>.

<sup>2</sup> Ibid.

<sup>3</sup> Ibid.

<sup>4</sup> Rowland W. Nothing about us without us: Inside the Disability Rights Movement of South Africa. Pretoria: Unisa Press; 2004. [https://uir.unisa.ac.za/bitstream/handle/10500/19447/Rowland\\_W\\_1868882596\\_Section1.pdf](https://uir.unisa.ac.za/bitstream/handle/10500/19447/Rowland_W_1868882596_Section1.pdf).