



Independent observer
of the Global Fund

UNITAID: KEY INNOVATION PARTNER OF THE GLOBAL FUND

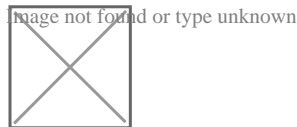


Image: Unitaid's strategic objectives

In two previous articles this year (see [Part 1](#) and [Part 2](#)), GFO analyzed some of the similarities and differences among four of the largest multilateral global health financing mechanisms: the Global Fund, [Gavi, the vaccine alliance](#), the [Global Financing Facility in Support of Every Woman Every Child](#), and [Unitaid](#). In those articles, we discussed where there are some notable overlaps among donors and recipients of the mechanisms, where there is alignment across strategic objectives, and how they distinguish themselves from each other in approach, scope and engagement with civil society and impacted communities.

Building on this reporting, GFO offers this focused profile of Unitaid, which has deep synergies with the Global Fund. There are good reasons for Global Fund stakeholders – particularly those involved with funding request development and implementation planning – to be aware of how Unitaid works and what that can mean for HIV, TB and malaria programs at country level.

As described in the opening of its [2017-2021 Strategy](#), “Unitaid’s mission...is to maximize the effectiveness of the global health response by catalyzing equitable access to better health products.” A three-pronged approach operationalizes this mission: Innovation, Access, and Scalability. Using a much smaller budget (average \$250 million per year) than the Fund or Gavi, Unitaid can be thought of as more laboratory and less implementer. Where the Global Fund supports programs through which products and

services are delivered to large populations, Unitaïd supports smaller-scale initiatives to see how new and innovative health products and delivery approaches can overcome barriers and achieve the most impact.

“We are small but highly maneuverable and operate like a speed boat,” said Unitaïd’s Executive Director, Lelio Marmora. “That allows us to explore uncharted waters and act as pathfinders for the Global Fund and other big entities that are more like aircraft carriers in scale.” To oversimplify: Unitaïd tests, the Fund delivers.

One word that can be used to describe Unitaïd is catalytic. “We can take bigger risks than others can,” said Sanne Fournier-Wendes, Senior Advisor to the Executive Director at Unitaïd. Unitaïd can try out promising but untested ideas, or help generate the evidence to inform World Health Organization (WHO) guidelines or national programs which are then referenced by the Fund or others. The Global Fund, on the other hand, is not built for risk-taking; the Fund channels money to proven interventions for maximum impact. As such, the Fund’s success relies heavily on innovators like Unitaïd, particularly in those treatment and prevention areas which are less “tried and true.”

Key programs

Unitaid currently has 40 active grants, with investments totaling about \$800 million, which aim to “identify cutting edge innovations in [HIV, TB and malaria] and beyond,” said Fournier-Wendes. Unitaid’s recent open calls for proposals reflect some of their top priorities, including multidrug resistant TB (MDR-TB), access to malaria treatments, HIV self-testing, and low-cost licensing and generic pharmaceutical production through TRIPS (trade related aspects of intellectual property rights) flexibilities.

endTB project

One of the most challenging aspects of the response to TB – for public health officials and patients alike – is MDR-TB. The common treatment regimens for MDR-TB are completely inadequate: They are long (up to two years), they are toxic (causing severe and lasting side effects), and they are often ineffective.

“The [endTB](#) project aims to find better, shorter and less toxic treatments for MDR-TB,” said Eva Nathanson, who oversees Unitaid’s TB and malaria portfolios. The endTB project – a clever acronym for Expand New Drug Markets for TB – aims to ensure access to two new TB drugs for countries who need them but cannot afford them. The two drugs, bedaquiline (developed by [Janssen](#)) and delamanid (developed by [Otsuka](#)), are the first new TB drugs to come to market in 50 years. According to Unitaid, which works with [Partners in Health](#) on the project, “the treatment regimens for the new drugs are shorter than the existing MDR-TB regimens and are presumed to be more effective and less toxic.”

While Unitaid and endTB are not behind the development of these drugs, they are at the forefront of understanding the market for the drugs, and the development of optimal treatment regimens, particularly in resource-limited environments. The project is currently working in 17 low- and middle-income countries, all of which have active TB grants from the Global Fund, where about 1,500 MDR-TB patients have been enrolled in an observational study looking at feasibility of the two regimens. The 17 countries are Armenia, Bangladesh, Belarus, DPRK (North Korea), Ethiopia, Georgia, Haiti, Indonesia, Kazakhstan, Kenya, Kyrgyzstan, Lesotho, Myanmar, Pakistan, Peru, South Africa and Viet Nam.

“The preliminary outcomes are promising, said Nathanson. “We have just witnessed remarkable progress in two countries, Lesotho and Georgia, where patients, care-givers and health care personnel are thrilled by the improved treatment outcomes and less toxic treatment for patients.” The next phase will be a clinical trial in six countries looking at the performance of these treatments against conventional TB treatment.

As Nathanson sees it, an important outcome of the endTB project – should the findings indicate that the new treatments are superior and deliverable – would be new WHO guidelines for MDR-TB treatment. These guidelines would then form the basis of TB program planning in Global Fund recipient countries and beyond. In addition, Unitaid communicates directly with the Fund’s Technical Review Panel to keep them up to speed on developments and product lists. Unitaid personnel also occasionally join Global Fund country teams on missions to better

understand how Unitaid project results are applied, and what local priorities and challenges are. Thus the project is being implemented with an eye towards feasibility in Global Fund-supported contexts, both from a technical review and procurement angle as well as grant implementation at country-level.

ACCESS-SMC project

“The [ACCESS-SMC](#) project has been vital to gaining evidence on the effectiveness of malaria prevention among children,” said Nathanson. The project has so far proven the feasibility, safety and effectiveness of seasonal malaria chemoprevention in the countries of West Africa and the Sahel where malaria transmission is strongly linked to distinct rainy seasons. (The Sahel, a transitional region between the Sahara in the north and the savannahs to the south, spans a number of African countries.) The ACCESS-SMC project ensured that 6.4 million vulnerable children across the Sahel received malaria prophylaxis in 2016.

ACCESS-SMC, in which Unitaid is partnering the [Malaria Consortium](#), is another example of Unitaid’s catalytic approach. There were indications that seasonal malaria chemoprevention (SMC) could have a substantial positive impact for children in areas where there is seasonal malaria risk, rather than year-round, such as in the Sahel region. But funders were hesitant to invest in SMC because it was an unproven intervention. Unitaid was able to take the risk and implement large scale roll-out of SMC in Sahel and demonstrate that the intervention was feasible, safe and effective, thus opening the door for longer-term financing to bring SMC to more children. “Out of seven SMC project countries, four (Gambia, Guinea, Mali and Niger) have secured Global Fund financing for SMC in 2017,” said Nathanson, indicating that pediatric malaria prevention is headed for scale-up around the region in the near future.

How the Fund and Unitaid interact

Unitaid and the Global Fund have an exceptionally synergistic relationship. “We work very closely with the Global Fund at all levels,” said Fournier-Wendes. In many cases, Unitaid tests new products or delivery approaches and the Global Fund scales up those that demonstrate impact. In practical terms, they are working with much of the same variables: Both focus largely on the same three diseases, and are working in many of the same countries; six of the Fund’s top ten recipients are also in Unitaid’s top ten. At the country-level, Unitaid requests its grantees work with CCMs to encourage countries to include successful products in funding requests and national strategies.

One strategic area in which the Fund and Unitaid work very closely is market-shaping. “Market-shaping” generally refers to the intervention of non-market actors, such as NGOs or funders, to help clear or mitigate hurdles to the introduction, distribution or acceptance of new products. In 2014, the organizations [signed a collaboration agreement](#) regarding a shared market-shaping agenda, which has been updated since. Their market-shaping also relies on the upstream/downstream roles the organizations inhabit, with Unitaid focusing on demonstrating feasibility or demand-generation for products and approaches, and the Fund providing the resources to bring interventions to scale. The Fund’s immense purchasing power is then further leveraged for affordability for recipient countries, such as through [wambo.org](#), the Fund’s online procurement platform for PRs, in which Unitaid is also a co-investor.

STAR program

The ongoing [STAR program](#) (“Stimulating and shaping the market for HIV self-testing in Africa”) is a key example of how Unitaid and the Fund work synergistically, both in implementation research and market-shaping. According to the program’s webpage, the first phase of the STAR grant, which is implemented by Population Services International, “aims to evaluate the acceptability, feasibility, and impact of HIV self-testing among different populations in Malawi, Zambia and Zimbabwe, and generate information about how products for HIVST [HIV self-testing] can be distributed effectively, ethically, and efficiently.” The first phase of the program, which focused on providing proof of concept for HIVST in low- and middle-income settings, is wrapping up now.

According to the program’s manager, Heather Ingold, the results of STAR Phase 1 have been “very encouraging,” showing that tests can be accurately used by lay people, that demand is high, and that no social harms have been reported. The first phase of STAR found that HIVST reaches populations not already accessing services (44-52%

are men, 32-48% are adolescents and 21-31% are first time testers) and that HIVST increases the overall uptake of HIV testing. “We’re seeing people who self-test link to care earlier, and [we are seeing] that HIVST increases linkage to voluntary medical male circumcision (VMMC) for HIV-negative men, Ingold said.”

This first phase has already produced results for Global Fund grantees: three self-test products have received eligibility certification from the Unitaid /Global Fund [Expert Review Panel for Diagnostics](#), which means that they are able to be procured with Global Fund grant monies. The Phase 1 results also led to the WHO issuing normative guidance for HIVST in 2016, which has in turn helped to expand the number of countries which are including HIVST as part of their approach to HIV testing, prevention, and linkage to care. According to a [report](#) released on 25 July 2017 by Unitaid and WHO, 40 countries now included HIVST in their national strategies.

Phase 2 of this project has further implications for countries with Global Fund grants because it will help resolve two critical application issues, according to Ingold: “The total cost of test delivery needs to be further optimized, in addition to reducing the cost of the commodity; and a clear investment case must be built, including evidence of cost-effectiveness and impact of HIVST in closing the testing gap and on linking newly identified cases to treatment and care – as well as linking those found negative to combination prevention services.”

Phase 2 of the STAR program includes the addition of South Africa, Lesotho and Swaziland alongside continued work in the Phase 1 countries, Malawi, Zambia and Zimbabwe. More information on HIV self-testing is available at hivst.org.

Unitaid also has active market-shaping projects on the treatment side of the HIV response. Most recently, Unitaid partnered with the Government of Kenya to [announce](#) that a previously unavailable antiretroviral drug, dolutegravir (DTG), is being introduced as a new first-line option for people living with HIV in Kenya. According to the press release, “DTG has been the drug of choice for the last two years for people living with HIV in high-income countries,” due to its low toxicity and simple one-pill-daily regimen.

Unitaid is also supporting four clinical trials involving DTG to gather the evidence required to expand the use of DTG to patient populations in low-income countries. Without the intervention of Unitaid to support initial roll-out and associated data collection on feasibility of the regimen in Kenya, Kenyans living with HIV would wait up to several more years to access the improved ARV therapy, which has fewer side effects and is better tolerated than other regimens. As part of the initiative, Unitaid is also helping to introduce DTG in Uganda and Nigeria this year. Pending the results of clinical trials which will inform WHO treatment guidelines, it will likely become a major product procured with Global Fund grants moving forward.

Finally, there are even strong connections between the Fund and Unitaid from a human resources and facilities standpoint. The Executive Director, Lelio Marmora, and a number of other staff at Unitaid spent earlier parts of their careers at the Fund. Prior to joining Unitaid, Mr. Marmora oversaw the Africa and Middle East department at the Fund. Today both organizations are on the same campus in suburban Geneva. And they will both be moving to the new Geneva health campus with Gavi and the Stop TB Partnership in 2018.

Unitaid is a resource for the Global Fund, other funders – including PEPFAR – and disease-response planners and implementers. As Global Fund country teams and country-level stakeholders develop funding requests and reprogram grants, they would be well-served to keep abreast of Unitaid’s work and results, particularly innovations in the pipeline, so as to be able to incorporate some of the most relevant and optimized HIV, TB and malaria treatment, prophylaxis, and diagnostic products and approaches. Because the products and approaches are pursued with Global Fund implementation in mind, implementers may find Unitaid results some of the most practical and applicable around.

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