



GREATER IMPACT through policy and partnership

It is the commitment of our partners that allows us to reach further, faster, in delivering new, improved TB treatments.

TB Alliance is a not-for-profit [product development partnership](#) and is uniquely positioned to leverage a global network of public and private collaborators to most efficiently drive the development and market availability of new TB treatments.

Indeed, it is because and with our partners, that we have been able to achieve success in 2015.

Partnerships are especially critical given the scarce resources currently allotted to the development of new tools and technologies for TB. Funding of TB research, according to the updated Global Plan to Stop TB, has stagnated to [about a third of what is necessary](#).

This is out of alignment with the ambitious plans that world leaders have issued over the past year to tackle TB. The United Nations' new [Sustainable Development Goals](#), (which have transitioned from the Millennium Development Goals) explicitly call for the end of the TB pandemic by 2030. Similarly, the World Health Organization

issued its new [End TB Strategy](#), also setting elimination targets. Meanwhile, a [plan to combat drug-resistant TB](#) was recently issued by the U.S. White House. All of these plans acknowledge the central role of new treatments to elimination efforts.

Still, these actions have yet to translate into the necessary increases in funding to achieve the ambitious goals laid out by world leaders. If nothing further is done to stop the pandemic, it will cost the world a cumulative \$16.7 trillion in the next 35 years, finds a [report](#) on antimicrobial resistance.

Despite the challenges, in 2015, TB Alliance made critical inroads in reaching some of the previously most unreachable populations of those suffering from TB. To do this, we brokered a number of new partnerships and strengthened existing ones. It is the commitment to our mission, vision, and work that our partners — be it [donors](#), [drug development partners](#), [advisors](#), and others — that we can reach further, faster, in bringing improved new TB treatments to the people who need them.

Reaching Further: for Children

In 2015, TB Alliance and partners announced the launch of new, child-friendly TB treatments in the appropriate doses.



The development and availability of child-friendly TB treatments was largely funded by [UNITAID](#), with supportive funding from [USAID](#), Australia's [DFAT](#), United Kingdom's [DFID](#), and [Irish Aid](#). This support means that, for the first time, there is now appropriate treatment for children with drug-sensitive TB, helping a population that has been utterly neglected.

However, it's not enough to develop needed treatments — we need to ensure they reach children in need. We would like to thank our project partner, [WHO](#), for their work to support the policy, regulatory and uptake work needed to accelerate the availability

of the products and [Macleods](#), the first manufacturer of the fixed dose combinations, which came to market ahead of schedule.

Additionally, collaboration with [Baylor University](#), [The Global Fund to Fight AIDS, TB, and Malaria](#), [KNCV](#), [Management Sciences for Health](#), [Medicins sans Frontieres](#), [Stop TB Partnership](#), and [UNICEF](#), and many others, will help accelerate adoption and use in high TB burden countries, helping us to achieve our collective goal of improved treatment of and child survival from TB.

Reaching the neglected children

There is still much that is needed to improve the treatment of children. Through 2016/2017, we will continue to work in partnership to prepare for the introduction of additional medicines to improve the toolkit for pediatric TB, including correctly dosed and child-friendly formulations of ethambutol, often recommended in countries with a high prevalence of TB/HIV, and isoniazid, recommended for preventive therapy.



Community Engagement

TB Alliance worked with its Community Engagement (CE) partners to create a school-base curriculum and a [suite of educational materials](#) to improve knowledge about TB among children. In addition to lessons in the classroom, children had a chance to create a mural in their local community to raise awareness of the disease. Other CE efforts this year included a [toolkit](#) that captures and measures the impact of community and stakeholder engagement activities on clinical trial activity.

Reaching further: communities and patients

Without community, research is not optimal. TB Alliance partners with sites to invest in [community engagement](#) (CE) programs, with the goal of empowering communities and patients with improved knowledge of TB so they can have a voice in the research process. Over the past year, we increased our investment to ensure sites that conducted late-stage research had companion CE programs. This meant that, over the past year, we engaged with 25 research sites to support and develop CE programs as part of our small grants program.

TB Alliance is committed to work with other sponsors to share best practices in CE. In 2015, we partnered with [AVAC](#) and [IAVI](#) to create a Global Health Community Engagement Forum, the first forum of its kind, which took place September 27-29 in Johannesburg, South Africa. The Forum included more than 80 CE implementers across diseases, research sites, and networks to build a stronger, more strategic, and better understood community of participatory and stakeholder engagement practice.

Above all else, we thank the patients who participate in our clinical trials. Without their participation, we could not advance the development of new treatments and create a TB-free future.



Reaching for expanded support

Over the past year, TB Alliance achieved a number of partnerships with donors that allow it to accelerate new treatments for those in need.

This included a new five-year grant from the [Bill & Melinda Gates Foundation](#); additional support from [DFID](#); and a five-year grant from the [Dutch Ministry of Foreign Affairs \(DGIS\)](#), which is once again supporting TB Alliance.

The US FDA reinitiated support for TB Alliance's [biobank](#) with a two-year agreement to fund specimen collection; support from [GHIT](#) was expanded for discovery work; and TB Alliance received its first grant from the Indonesian Health Fund, comprised of individual donations from business leaders in Indonesia. This grant allows us to progress work that builds the country's capacity to fight the TB epidemic and is especially important in light of new evidence that the prevalence of TB is much higher than previously estimated.

Reaching deeper: growing the pipeline

It is through collaboration and partnership that TB Alliance has significantly expanded its efforts to discover new compounds that hold the promise to become tomorrow's TB cures.

Through our partnership with the [TB Drug Accelerator](#) (TBDA) consortium, we are experiencing heightened engagement with research organizations involved in TB drug discovery and pre-clinical development. The TBDA is presently a collaboration of eight pharmaceutical companies, eight academic universities, and TB Alliance which are working together to expand the number of candidates coming into the pipeline in the coming years by pooling capabilities, platforms, and expertise of member organizations. In particular, TB Alliance would like to recognize the contribution of [Eli Lilly](#), which is dedicating in-kind support in conducting a GLP toxicology program. [AbbVie](#) has also contributed in-kind support for advancement of pre-clinical compounds.

We have also successfully grown our partnerships in Japan, with help and funding from GHIT, including new partnerships formed with [Chugai](#), [Daiichi Sankyo Novare](#), [HyphaGenesis](#), [Mitsubishi-Tanabe](#), [OP-Bio](#), and [Sumitomo-Dainippon](#). In Indonesia, TB Alliance has established a new partnership with [Universitas Gadjah Mada](#), funded by the Indonesia Health Fund.

These partnerships complement our other collaborations with large pharmaceutical and smaller companies, and academic institutions. In 2015, [Roche](#) and [Schrödinger](#) joined TB Alliance's roster of partners. To find out more about this work, click [here](#).

Reaching further: through research partners

Without our global network of research sites, we could not run the clinical trials needed to achieve improved TB treatments. Sites that participate in TB Alliance studies are located around the world, on the front lines of care of clinical trial participants. We are indebted to their work. In 2015, we would especially like to recognize the sites in Uganda, Tanzania, and South Africa which participated in the [NC-005](#) trial, which completed enrollment for the Phase 2b trial.

The past year also marked the 5th Anniversary of the [Critical Path to TB Drug Regimens \(CPTR\) Initiative](#). Co-lead by TB Alliance alongside the [Critical Path Institute](#) and the Bill & Melinda Gates Foundation, the Critical Path to TB Drug Regimens has helped advance a wide variety of tools, models, and approaches to support the acceleration of TB drug development, spur and coordinate the development of complementary technologies, and to better evaluate clinical data to help inform trial design and prediction.

In 2015, CPTR and the WHO's Special Programme for Research and Training in Tropical Diseases (TDR) have partnered to help maximize the knowledge and understanding gained from completed Phase 3 TB drug clinical trials. The partnership brings together an expert steering committee to analyze three contemporary Phase 3 trials ([REMox TB](#), [Rifaquin](#), and [OFLOTUB](#)), to improve understanding of fluoroquinolone-containing shortened regimens for drug-susceptible TB. Through this collaboration, we expect the development of new tools to optimize the design of future TB trial design. Most notably, CPTR's work led to the endorsement of the in vitro hollow fiber system of tuberculosis (HFS-TB) — a preclinical model to evaluate TB drugs individually or in combination — by leading regulatory authorities, including the [European Medicines Agency](#) (EMA) and the [United States Food and Drug Administration](#) (FDA).

Global network of partners

