

Lighting the Path

2022 Annual Report

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About TB Alliance

The world is in desperate need of improved, faster-acting and affordable tuberculosis drug regimens that are available to all who need them. These new cures can bring renewed health, hope and prosperity to millions. Since our inception in 2000, TB Alliance has contributed to the global search for and development of new TB drugs and regimens, catalyzing the field and convening cross-sector partnerships to forge the progress that is urgently needed for better TB treatments.
[Learn more about TB Alliance here.](#)

We live in an age of pandemics.

“We are fighting for a future in which everyone with TB can be treated with the safest, shortest and most effective regimens possible” – Dr. Mel Spigelman, president and CEO, TB Alliance

Unfortunately, TB remains the leading cause of infectious disease death – killing about 1.6 million people in 2021 alone.

The TB pandemic won't end without innovative approaches to developing new tools to prevent, diagnose, and treat the disease, coupled with a commitment to universal access putting new tools into the hands of all who need them around the world.

“In recent years, we've seen what's possible. Not only can a small nonprofit organization develop and deliver a transformative new regimen for drug-resistant TB, but we've also seen what the world can do when we address a global health issue head on.” – David Norton, new Chair of the TB Alliance Board of Directors

2022 At A Glance

- The World Health Organization (WHO) updated its treatment guidelines for drug-resistant TB, allowing for nearly all DR-TB patients globally to receive short, six-month, all-oral regimens.
- A new study found that the BPaL/BPaLM treatment regimens could save governments up to US\$740 million annually.
- TB Alliance fostered a new access partnership to help pave the way for expanded access to shorter, more effective, treatment regimens for DR-TB patients globally.

Science

In recent years, advancing the fight against TB has taken a new kind of approach in drug development, which is a consortia-based approach.

These consortiums bring together research partners around the world to pool resources and expertise to help advance the discovery and development of potential new drug candidates and compounds.

We must constantly look toward new, innovative approaches to finding solutions for the world's most difficult global health problems.

Impact

To date, more than 50 countries have procured the six-month, all-oral BPaL regimen to treat over 7,000 people with drug-resistant TB.

Building on evidence generated by TB Alliance and its partners, the World Health Organization has prioritized 6-month, all-oral treatments as the new standard for DR-TB treatment.

Community

TB Alliance is always seeking innovative ways to advance the fight to end TB – whether through work in consortia, open-source drug development, or our Community Engagement program.

As we expand access to the presently available improved treatments, we are equally committed to finding the next compounds and regimens that will have a profound impact on the TB pandemic. Without new partnerships and relentless innovation, the world's most difficult global health problems will continue to go unsolved.

Science

ZeNix Trial Results Published in the *New England Journal of Medicine*

The results of TB Alliance's Phase 3 ZeNix clinical trial revealed that the [BPaL treatment remains effective](#) against highly drug-resistant strains of TB with reduced dosage and/or duration of the linezolid component of the regimen. Along with the maintenance of efficacy, there was a decrease in linezolid-associated side effects that accompanied the reduced dosage or duration of linezolid. The results from the trial were published [in the *New England Journal of Medicine*](#). ZeNix enrolled 181 participants at 11 sites across Georgia, Moldova, Russia, and South Africa. The results contributed to new WHO treatment guidelines issued in 2022.

ZeNix: An Open-Label, Four-Group Study

THE RESULTS

93.4% of all participants completed the full course of treatment



89% of all participants had favorable outcomes



Bacteriological and Clinical Resolution
6 months after end of therapy

Favorable outcomes

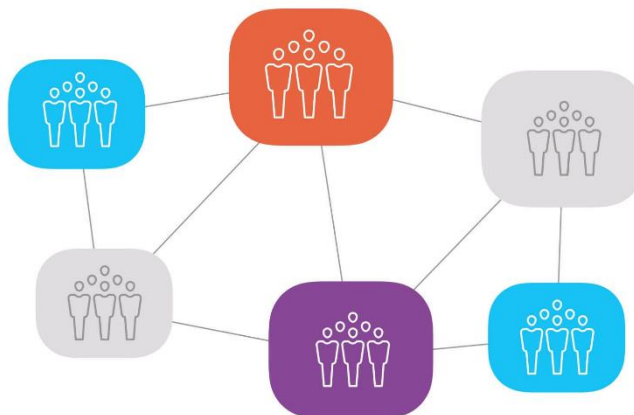


TB Alliance Spearheads Open Development Model with TB Drug Candidate, Sutezolid

TB Alliance has implemented an open development approach to advance the Phase 2 TB drug candidate, sutezolid, which could be a component of a next-generation TB regimen. We have made sutezolid available for study by all researchers who commit to making their results available to the broader TB research community. This novel approach has contributed to three clinical trials that are expected to begin in 2023.

Working with Consortia

There is a constant need to innovate in finding solutions to the world's most difficult global health problems. In recent years, advancing the fight against TB has taken a new approach in drug development, which is a consortia-based model. TB Alliance is involved in several consortia – including the Innovating Health Initiative (formerly Innovative Medicines Initiative), which runs programs like EU-PEARL, UNITE4TB, EAR4TB, and the IMI AMR Accelerator. TB Alliance is also a member of PAN-TB, a consortium led by the Bill & Melinda Gates Foundation. These consortia bring together research partners around the world to pool resources and expertise to help advance the discovery and development of potential new drug candidates and compounds. Innovative funding mechanisms like these consortiums are more critical than ever before, as the COVID-19 pandemic shined a light on both the [urgent need for increased R&D](#) of new drugs, vaccines, and diagnostics to combat emerging and re-emerging diseases and the need for innovative partnerships in discovering, developing and delivery new tools.



BENEFIT Kids

It is currently estimated that 30,000 children develop drug-resistant TB (DR-TB) annually, but fewer than 10-15% are treated. Even for children who can access treatment, current regimens are still too long, complex, toxic, poorly tolerated, and simply not acceptable. The BENEFIT Kids program, funded by UNITAID and led by Stellenbosch University in collaboration with TB Alliance, aims to address this lack of high-quality evidence on and access to prevention and effective, tolerable treatment of DR-TB in children. In December 2023, BENEFIT Kids launched a [series of pivotal publications](#) in the *International Journal of Tuberculosis and Lung Disease* (IJTLD) highlighting the importance of child-friendly formulations for DR-TB, including extemporaneous formulations for pretomanid, delamanid, clofazimine, and bedaquiline.

Spotlight: The Project to Accelerate New Treatments for Tuberculosis

The Project to Accelerate New Treatments for Tuberculosis (PAN-TB) collaboration [announced a program](#) to support the progression of two investigational TB combination treatment regimens into Phase 2 clinical development. The collaboration will evaluate whether the novel regimens, which combine registered products and not yet approved new chemical entities, can effectively treat active pulmonary TB using substantially shorter treatment durations than existing drug regimens, with the goal of identifying a regimen suitable for Phase 3 development.

Impact

BPaL/M Included in Updated WHO Guidelines for DR-TB Treatment

Building on evidence first developed by TB Alliance, [almost all patients with DR-TB can now be treated](#) in six months with an all-oral regimen. New [World Health Organization \(WHO\) guidelines](#) allow for the programmatic implementation of treating almost all forms of drug-resistant tuberculosis (DR-TB) with either BPaLM (a combination of bedaquiline, pretomanid, linezolid and moxifloxacin) or BPaL (bedaquiline, pretomanid and linezolid).

The Ukraine Experience: Implementing the BPaL Regimen

Ukraine was the first high-burden country to adopt the BPaL regimen, enrolling patients beginning in December 2020. A shortened, simplified treatment for DR-TB has been an especially welcome advance for patients who needed treatment amid wartime conditions. As the war began in February 2022, 50 Ukrainian patients were given the remainder of their full treatment course so the remaining duration of their treatment could be completed remotely. 47 of 50 such patients were successfully monitored, all of whom successfully completed treatment. Overall, more than 90% of Ukrainian patients who completed DR-TB treatment with BPaL 6+ months ago remain TB-free, a finding consistent with clinical studies of the regimen. These outcomes would have been extraordinarily difficult using the longer, more toxic, and less effective treatments that were in place prior to BPaL. Ukraine's National TB Program is now moving quickly to scale up access to BPaL on a nationwide basis. Despite the ongoing invasion by Russia, patients on BPaL in Ukraine have been able to continue their treatment even when TB hospitals were under assault or even destroyed.

Life-saving and Cost-saving

A new study published in [PLOS Global Public Health](#) found that the BPaL/BPaLM treatment regimens that are now included in the WHO guidelines for the treatment of DR-TB could save governments up to US\$740 million annually, which is enough to fund almost another year's worth of DR-TB treatments for more than 400,000 people. The study estimates that the cost of implementing this therapy is potentially 40-90% less expensive than current regimens.

LIFE SAVING, COST SAVING

34%
reduction in price
of pretomanid



At the end of 2022, TB Alliance also entered into a [new partnership with Viatris and MedAccess](#) to reduce the price of pretomanid by 34%. This price reduction will help pave the way for further expanded access to highly effective, pretomanid-containing treatment regimens for DR-TB patients globally.

The Year in Photos

2022 was a year that marked progress throughout the organization. TB Alliance saw developments in strengthening and developing our research pipeline, but we've also seen progress in delivering treatments by ensuring that people around the world have access to shorter, more effective regimens for drug-resistant TB.

[Browse the entire gallery on Pixieset](#)



Spotlight: Volodymyr's Story of TB Courage in Ukraine

Volodymyr was a resident physician in Kyiv in February 2021 when war broke out in Ukraine. He was diagnosed with tuberculosis after two weeks of cough and fever. "Around February 20th, I was dismissed with the prescribed treatment, with the BPaL method." When Russia invaded Ukraine, Volodymyr, "didn't believe it." He said, "I woke up to my parents, they said: 'Are you kidding us? It can't be true. A war? With Russia? Why?' And on February 25th, we were already under occupation." Volodymyr only had enough antibiotics for two weeks, but his doctor was able to send him more medicine for another month. Reflecting on living with TB under wartime conditions, he said, "In general, things that were difficult in peacetime, are ten times more difficult in wartime [...] If [treatment] lasts for a year, two, one and a half, it will be more difficult in such situations."

Community

Connecting with Partners

TB Alliance colleagues joined in-person events around the world throughout 2022 to collaborate with partner organizations and other experts to help advance efforts to end TB and hold discussions on pandemic preparedness. Dr. Mel Spigelman, TB Alliance's President and CEO, participated in the World Health Summit in October 2022 and joined partners from the WHO, the Stop TB Partnership, FIND, TAG, and others for an event on the importance of investing to end TB.

Health for All

More than three years after the start of the COVID-19 pandemic, the critical importance of investing in biomedical R&D to achieve Health for All has become more apparent than ever. The remarkable efforts witnessed throughout the COVID-19 pandemic also exposed serious gaps in equitable access to health tools, technologies, and services, which have had a negative impact on key areas of development. During the [77th Annual UN General Assembly Science Summit](#), TB Alliance joined MMV (Medicines for Malaria Venture) and DNDi (Drugs for Neglected Diseases *initiative*) in holding a side event on how scaling up investments in biomedical innovation and equitable access is necessary to achieve Health for All, which in turn drives sustainable development.

TB Alliance was Honored to Receive GHTC's Innovating for Impact Partnership Award

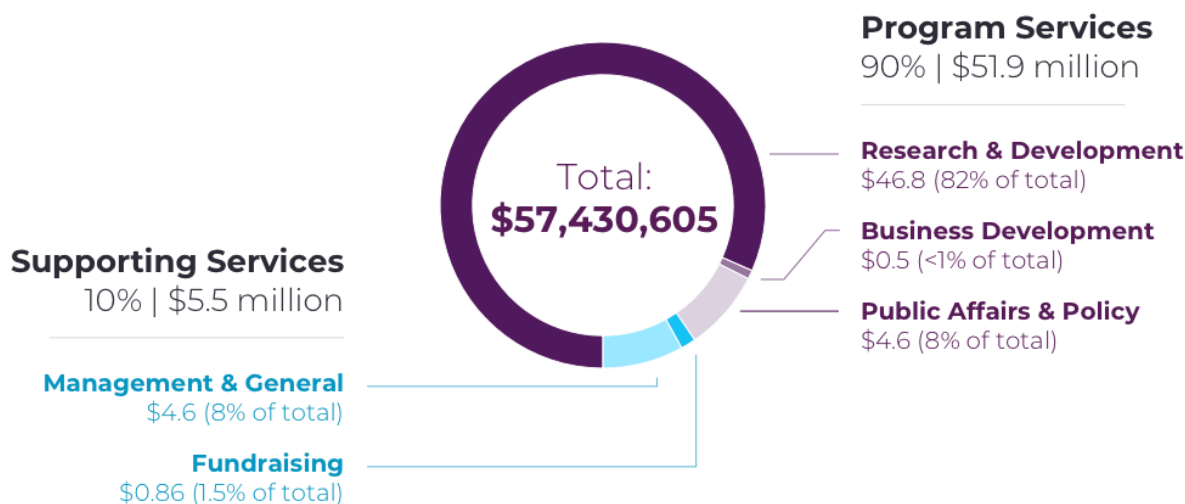
The development and subsequent introduction of pretomanid and the BPaL regimen is a signature organizational achievement that wouldn't have been possible without the committed and invaluable partnership of a constellation of funders, researchers, local communities, and clinical trial participants around the world. In December of 2022, TB Alliance and partners, including USAID and the US NIH were honored with the Global Health Technology Coalition's *Innovating for Impact Partnership Award*, recognizing the importance of the development of this urgently needed new DR-TB therapy.

One of the interventions that we're celebrating tonight – the extraordinary achievement of getting that combination of anti-tuberculous drugs. We have pretomanid, which we're celebrating tonight, together with bedaquiline and linezolid, which has really transformed a field that has really been sleepy in the sense of not having the advances that we've had with other areas. We're now essentially skyrocketing it into the 21st century.

– Dr. Anthony Fauci

Our Financials

As the COVID-19 pandemic continued to demand extensive global health resources, and economic uncertainty and calls for austerity pervaded, those suffering from TB and DR-TB remain imperiled and all too neglected. TB research funding shortfalls remain profound, with research funded at approximately a third of Stop TB Partnership's targets. Still, TB Alliance continued to advance new TB drug regimens and spearhead the introduction of pretomanid and the BPaL regimen at an unprecedented pace for a new TB therapy developed in the 21st century.



Spotlight: An Increasingly Global Workforce

TB Alliance is a not-for-profit product developer with a global mission – and we are continuing to reflect these principles in our organizational development and structure. This past year, we added new staff members based in strategic hubs from Washington DC, to Kyiv, Ukraine. With a need to ensure availability of our products wherever TB exists and with remote or hybrid teams becoming even more the norm, TB Alliance is increasingly capable of assembling global teams that include local expertise. The future is now – in both TB research itself and in how we work.



TB Alliance is indebted to its partners, especially all participants in our clinical trials, for the progress seen in 2022.