



Charting the Course

2021 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.

As you're reading this, TB is killing more people in many countries than COVID-19 – or any other infectious disease.

We've all come to know the power of infectious diseases – but we also know the power of science.

Science

We cannot end the TB pandemic without a revolution in science.

The COVID-19 pandemic has shown us that new tools, drugs, diagnostics, and vaccines can be brought to bear with the right amount of funding and political will.

People with TB deserve that same commitment.

In 2021, TB Alliance showed the power of science with ZeNix:

A clinical trial of a 6-month, all-oral regimen for highly drug-resistant forms of TB.

All four arms of the trial showed favorable outcomes, with an overall treatment success rate of approximately 89%.

We're bringing new weapons to the fight against TB.

Impact

Access to the latest treatment innovations is a human right.

1,845 patients in more than 31 countries accessed TB Alliance products for highly drug-resistant TB alone in 2021.

We cannot afford to stop until our treatments are available to everyone who needs them.

Community

Countries are falling short of global goals – COVID-19 has made that worse.

For the first time in a decade, the TB situation is getting worse, not better. More people are dying despite recent breakthroughs. Now is the time to recommit.

We work with many partners to achieve our vision of a world in which no one dies of TB. Please join the fight.

Learn how this year's progress will shape the course of the TB response for millions.



Mel Spigelman
President and CEO, TB Alliance

Science

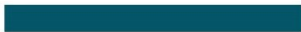
Putting Patients First

TB Alliance's [ZeNix trial](#) of the BPaL regimen (bedaquiline, pretomanid, and linezolid) in South Africa, Eastern Europe, and Russia sought to optimize a six-month, all-oral treatment regimen by assessing various dosing regimens of the linezolid component of BPaL. Presented at the 11th IAS Conference on HIV Science, the data demonstrate improvement in the safety and tolerability of the BPaL regimen with alterations in linezolid dosing. "The results of this study are very reassuring. With a reduction in the dose and/or duration of linezolid, we can still offer patients a high chance of cure in only six months," said Dr. Francesca Conradie, principal investigator for the ZeNix clinical trial, as well as South Africa's Clinical Access Program for the regimen.

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



Linezolid per day

1200mg

600mg

= 1 month

Reaching Those in Need

To date, 15 countries or regulatory bodies have approved pretomanid as part of the BPaL regimen for the treatment of patients with highly drug-resistant forms of TB, and regulatory applications have been submitted to another 17 countries and counting by Viatrix, one of TB Alliance's commercialization partners. A further 11 countries are actively enrolling patients in operational research to continue gathering evidence and implementing the regimen in other regions. The evidence generated from the Nix-TB and [ZeNix](#) clinical trials, which is now being replicated through operational research programs such as LIFT-TB, underscores the potential of short, all-oral, BPaL-based regimens for patients with highly drug-resistant TB.

Advancing TB Science

TB Alliance advanced the development of new TB medicines while navigating the spread of COVID-19 by pivoting research projects from labs within and across borders. As a global product development partnership with relationships all around the world, TB Alliance worked closely with our partners and researchers to advance both early- and late-stage research.

- Adding new projects in the [Lead Optimization](#) phase
- Advancing [TBAJ-587](#) to Phase 1
- Completing the process chemistry effort for [TBI-223](#)
- Publishing preclinical results on [TBAJ-876](#) showing shorter and more effective treatment over bedaquiline
- Finalizing and presenting results from the [ZeNix](#) Phase 3 trial



Recognizing Healthcare Heroes

In another year of unprecedented challenges, TB Alliance and its partners could not have advanced the TB drug research agenda without the healthcare and essential workers around the world who have worked tirelessly day after day to fight the COVID-19 pandemic and continue to help those impacted by health threats like TB. We are indebted to their work.

Spotlight: Making a Difference

Dr. Nosipho Ngubane is a clinical investigator in South Africa studying new treatments for patients with TB and HIV, including BPAL-based regimens. She is committed to helping develop shorter, more effective TB therapies because they “[could make a very big difference](#)” in the community and make it “easier for people to comply and take their treatment until the end.” TB Alliance relies on the dedication and insight of partners all around the world, like Dr. Ngubane, to help realize breakthroughs in TB care that can help overcome humanity’s longest pandemic.

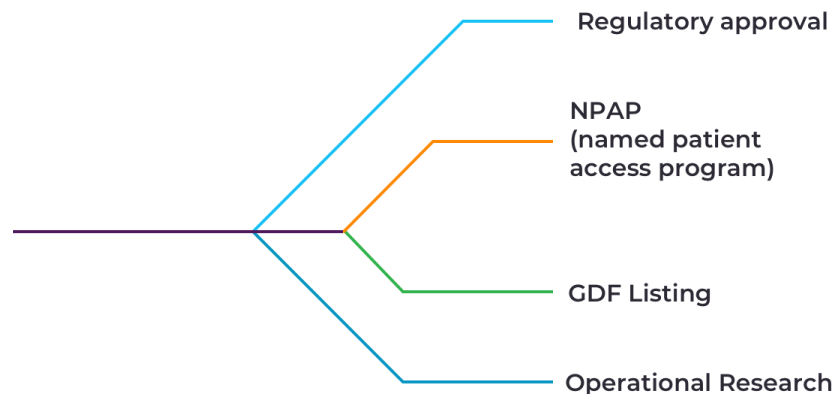
Impact

Changing the Landscape

Despite new challenges related to the COVID-19 pandemic, TB Alliance has increased access to pretomanid as part of the BPaL treatment regimen. Through our efforts and collaborations, we have accomplished the following:

- [More than 30 countries](#) have procured pretomanid and 15 regulatory bodies have granted approval.
- [176 countries](#), including all WHO top 30 high-TB-burden countries, can access pretomanid for use in the BPaL regimen through different pathways.
- TB Alliance has granted non-exclusive licenses to [four high-quality manufacturers](#) to ensure that every country and every person in need is able to access this treatment.
- BPaL is about one-third the current average cost of MDR-TB treatment. According to a recent study evaluating the [budgetary impact in three high-burden countries](#), the BPaL regimen can be highly cost-saving as compared with conventional regimens to treat patients with highly drug-resistant TB.

Pathways to Access



Leveraging Innovation

TB Alliance is working with partners around the world to ensure that patients who need it can have access to the BPaL regimen. One of the key initiatives in this effort is [LIFT-TB](#) (Leveraging Innovation for Faster Treatment of Tuberculosis), supported by the Republic of Korea through the Global Disease Eradication Fund. This program seeks to broaden the adoption of new treatments in seven countries most affected by drug-resistant forms of TB across Southeast and Central Asia, and Central Europe. As a result of these efforts to speed implementation, operational research (OR) has commenced in 12 countries. Ukraine was the first country to implement OR through LIFT-TB, and the first 120 patients enrolled in 2021 have already completed treatment. As presented at the 52nd Union World Conference on Lung Health, among the [first cohort of patients](#) recruited, 93% completed their six-month treatment and were sputum negative at the time of the assessment.

Securing the Future of TB Research

The rapid development and introduction of COVID-19 diagnostics, vaccines, and drugs has given the world a sterling example of what political will can look like in response to a deadly infectious disease. Tragically, the TB response stands in stark contrast: annual R&D funding targets – which represent a small fraction of the funding that has been devoted to fighting COVID-19 – are off the mark by more than half of what has been conservatively estimated to be needed. This shortfall puts TB innovation at risk, condemning millions of patients to antiquated therapies that can hasten the development of drug resistance. All countries with the capacity to fund TB research must do so if we are to live in a world in which no one dies of TB.

Fighting Dual Pandemics

The COVID-19 pandemic serves as a grave reminder that health threats, especially from airborne infectious diseases, are not bound by national borders and can travel swiftly across continents and oceans. This new pandemic has placed tremendous strain on health systems around the world and is undoing hard-won gains in the fight to improve global health. TB is preventable and curable, but for the first time in more than a decade, TB deaths are rising due to COVID-19. The impact that COVID-19 is having is proving to be detrimental in the fight to end the [age-old pandemic](#) that is TB: [1.2 million fewer people](#) were diagnosed with and treated for TB in 2021, and given that an estimated 5.7 million people received treatment for TB in 2020, this represents a drop of 21% as compared to the previous year, leaving millions untreated.



Spotlight: Overcoming Drug-Resistant TB

[Panganai](#) lives in Johannesburg with his family and young children. In 2019, he was diagnosed with multidrug-resistant TB, and he said, “When I heard that this was multidrug-resistant, I was very confused [...] I did not know how I was going to survive.” Panganai was initially placed on a long treatment regimen and was “taking 32 tablets every day.” He then joined a clinical trial testing a three-drug, all-oral, six-month regimen. “When I took it, my health was improving each and every day,” he said. Now, more than one year after the end of his treatment, Panganai is back home with his family and feeling “as healthy as before.”

Community

A Communal Effort Against TB

Ending TB is beyond the capacity of any one organization. TB Alliance's achievements are dependent on the work of an entire community of partners, including a diverse base of funders who share a vision of a world without TB.

In a year of tumultuous fiscal realities, TB Alliance deepened its relationships with long-standing supporters and strove to build new partnerships and expand our community of support. This includes securing grant extensions or new commitments from UK FCDO, USAID, KfW (Germany), DGIS (Netherlands), the Bill and Melinda Gates Foundation, and Irish Aid. Furthermore, we deepened our engagement with the Innovative Medicines Initiative (IMI) by joining the UNITE4TB program.

A pandemic of this scale requires a community with a coordinated and long-term vision to effectively combat it. Together, we can end TB.

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Building Research Capacity in Europe

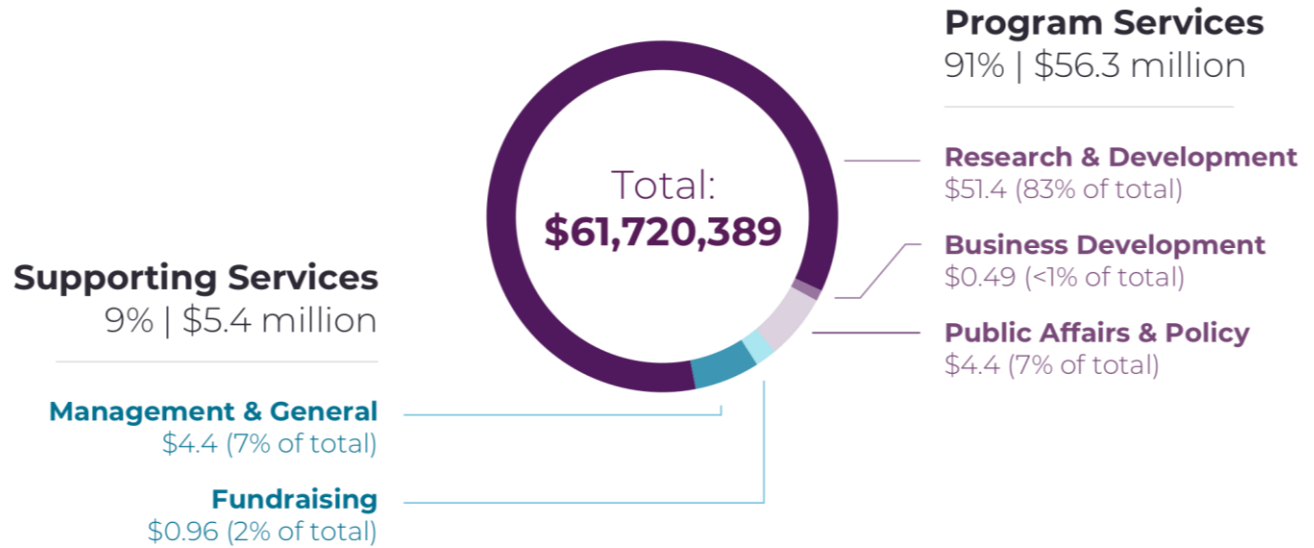
As part of the Innovative Medicines Initiative (IMI), TB Alliance works with partners in the research and development of new technologies and medicines to treat TB disease. TB Alliance has joined three projects under IMI: EU-Pearl, ERA4TB, and [UNITE4TB](#). In 2021, the [TBAJ-587 clinical trial](#), the first Phase 1 trial in humans conducted by TB Alliance through the ERA4TB project, completed the Single Ascending Dose and Food Effect cohorts. This research will shape TB Alliance's strategic approach to developing the next generation of TB treatments.

From Global to Local

A crucial aspect of successfully developing and delivering new and improved TB cures is working closely with communities that are impacted by TB. Through our [Community Engagement program](#), TB Alliance works with communities to promote open communication and participation in TB drug research and maintains a dialogue with community members to ensure all new treatments meet their needs. Throughout 2021, TB Alliance hosted a [series of five virtual forums](#) to share and hear updates from partners around the world. These webinars created a meeting space despite travel and safety restrictions and sought to minimize barriers to participation for those in low-resource settings.

Our Funding in 2021

In a year when more people died of TB than the year before – the first such year in a decade – TB research funding remained flat at [less than half of the global funding target of US\\$2.16 billion per year](#). Despite this persistent scarcity, TB Alliance has continued to advance its research and product delivery agenda based on the strength of its pipeline, funders, and partners.



TB Alliance is indebted to its partners, especially all participants in our clinical trials, for the progress seen in 2021.