MESSAGE FROM THE CEO

Dear Stakeholders, Partners, and Patients,

For TB Alliance, 2016 was a year of impact, where we saw pivotal research come to fruition and our first products reach the patients who need them.

Over the past year, countries began to purchase and roll out improved medicines for children that, for the first time, were in the correct doses and designed specifically for them. In the first year following launch, more than 326,000 treatment courses were ordered by 36 countries. That's enough to meet the needs of about 90% of the children reported to have TB and could be the most successful introduction of TB medicines to date.

For donors, partners, countries, and especially for families and children with TB, this represents a significant achievement and hopefully paves the way for a new era where new treatments are not only developed quickly, but also made available to children soon after their availability for adults.

"What we're on the verge of doing is really translating the results of 2016 into regimens that can be proven and implemented in the very near future, and hopefully be the source of saving millions of lives of TB patients."

—Dr. Mel Spigelman, President and CEO, TB Alliance

This year was also an incredibly important one for R&D activities. Currently, countries are fighting the TB pandemic, with suboptimal regimens, which have mostly been unchanged for decades. Results from TB Alliance's NC-005 and Nix-TB trials point to the possibility of a single, short and simple common therapy for virtually all people with drug-sensitive and multidrug-resistant TB, and a closely related treatment for those with extensively drug-resistant TB or XDR-TB. These tools would enable the dramatic scale-up needed so that every person with TB has access to simple, fast, effective, and affordable treatment.

The research and work underpinning these clinical development achievements started many years ago. Given the long lead time needed to discover and develop impactful new therapies, we cannot stop the search for the next breakthrough regimens. We are proud to report that, in terms of our discovery work, we have never had a more productive year. We have seen more drug candidates have been advanced into preclinical development in 2016 than in the past five years combined, and are hopeful that we can continue a steady stream of new drug candidates in the years ahead.

None of the above would be possible without strong support of all our partners, including donors, researchers from both the public and private sectors, governments, civil society organizations, and others, most of all the clinical trial participants.

We are having an impact — but there is much more to do. Please join with us as we strive to make the critical progress needed to realize the promise of new and better treatments for all TB patients.

Sincerely,

DR. MEL SPIGELMAN
President and CEO, TB Alliance

DR. CARLOS MOREL
Chairman of the Board, TB Alliance

CHILDREN AND TB

ACHIEVING OUR "AAA MANDATE": RAPID INTRODUCTION OF IMPROVED TB MEDICINES FOR CHILDREN

Each year, one million children get sick with TB and 210,000 die from it — that's nearly 575 children dying each and every day.

In 2016, TB Alliance and its partners made huge progress in the introduction of the first appropriately dosed child-friendly TB medicines. Previously, care providers and parents encountered many difficulties in administering suboptimal medicines to children every day for six months. In just one year, more than 325,900 treatment courses of these new medicines had been ordered — enough to meet the needs of 90% of the children reported every year to national programs. Today, 36 countries have ordered the improved medicines, with many more expected in the years ahead.

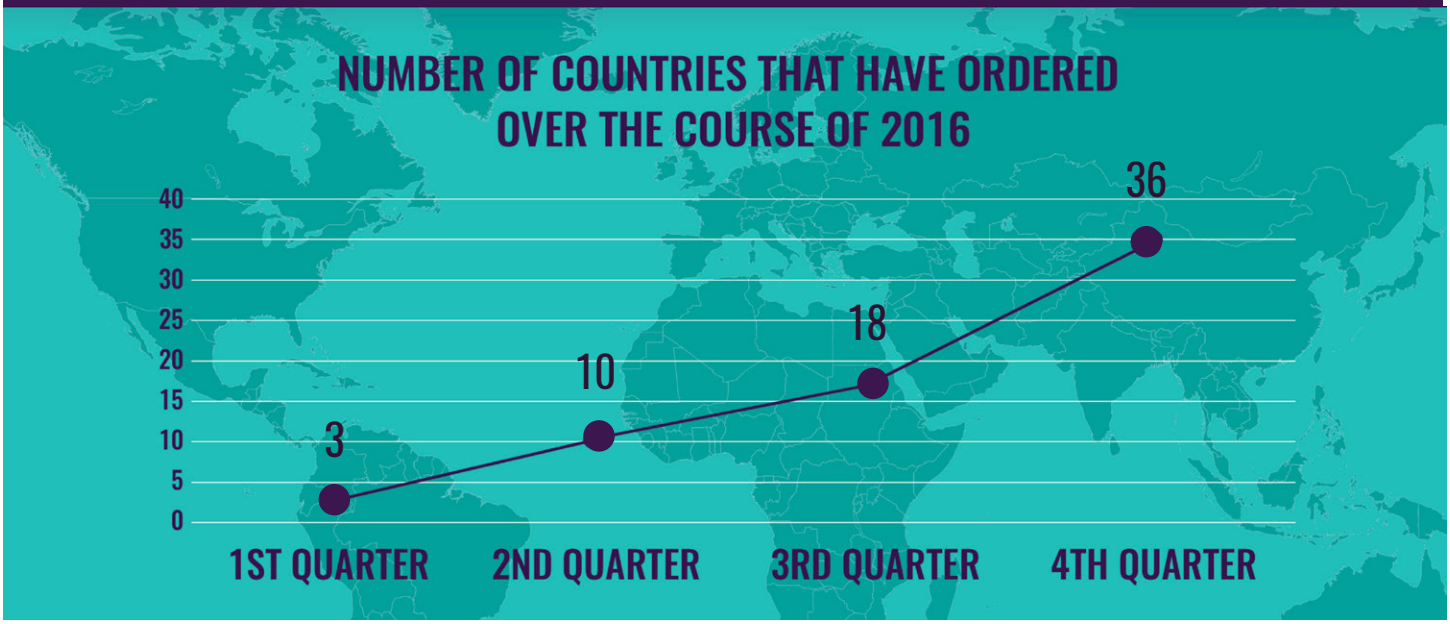
Early adopter countries have already received the medicines and begun dispensing them to children in need. In Papua New Guinea, a pilot was launched at Port Moresby General Hospital in August 2016 by the PNG Paediatric Society, along with the World Health Organization, Australian Aid, Ministry of Health, National TB Program, and other partners — Papua New Guinea was among the first countries to receive a shipment of the new treatments, followed closely by Kenya, which became the first country to make them available on a national level.

In 2017, other countries that are expected to begin dispensing the medicines include India, in a major pilot of 100 districts across five states, and the Philippines. Additional countries that have now received these new treatments include Pakistan, Afghanistan, Bangladesh, and Myanmar.

The rapid introduction of these improved childhood TB medicines may be the most successful TB product launch in history. The new childhood TB medicines also achieved the TB Alliance patient access commitment, known as the "AAA Mandate." These new medicines are easily adoptable as they are endorsed by WHO treatment guidelines, widely available in the public and private sector, and affordable.

As countries continue to roll out these products, children around the world stand to benefit from dramatically improved TB treatments. As countries continue to roll out these new products and with others on the horizon, the continued work of TB Alliance and its partners will be important to ensuring that children with TB are not neglected.

In just one year, more than 326,000 treatment courses of these new medicines had been ordered — enough to meet the needs of 90% of the children reported each year to national programs.



Results through Strong Partnerships

Throughout 2016, TB Alliance continued to work with a network of technical partners to ensure that the new formulations reach every child in need. In additional to country partnerships, global partners include the World Health Organization, MSH/SIAPS, UNICEF, the Stop TB Partnership's Global Drug Facility, Childhood and Adolescent TB Working Group, The Global Fund to Fight AIDS, Tuberculosis, and Malaria, Desmond Tutu TB Centre, USAID, KNCV, The Union, and Baylor College of Medicine, among others.

This initiative received support from UNITAID, the major funder, as well as US Agency for International Development (USAID), the UK Department for International Development (DFID), Irish Aid, the Australian Department of Foreign Affairs and Trade (DFAT), and the Dutch Ministry of Foreign Affairs (DGIS).

SUBSTANDARD TREATMENT

BIG PILLS/
CRUSHED PILLS

BROKEN PILLS/
BAD TASTE

NEW MEDICINES

SMALL
TASTE GOOD

FRUIT-FLAVORED
WATER-SOLUBLE

Kenya Launches Improved Medicines for Children

"Now, with the appropriate treatments, we can make rapid progress in finding and treating children with TB so we can achieve a TB free generation."

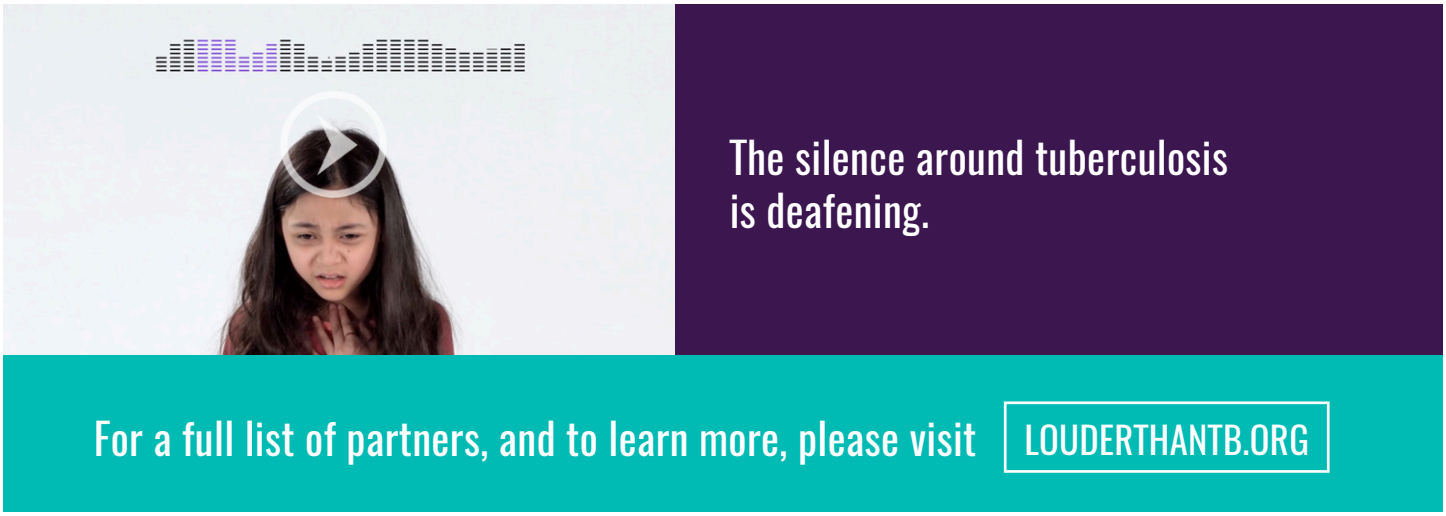
—Dr. Cleopa Mailu, Cabinet Secretary for Health, Kenya

GETTING #LOUDERTHANTB

On World TB Day 2016, TB Alliance organized the launch of Louder Than TB, a global campaign composed of more than 40 organizations, with its first goal to raise awareness of childhood TB and improve case finding, treatment, and overall child survival from TB.

In addition to organizations that have been active in the field of TB, UNICEF, Save the Children, PepsiCo, the ONE campaign, and other groups have joined as part of the Coalition of organizations working to help the campaign reach its goals. FCB Health, a global healthcare advertising agency, is donating its professional services, ensuring that the campaign runs in a very cost-effective manner and with maximum impact.

Kenya Awareness Poster Generated by Louder Than TB Campaign



DISCOVERING TOMORROW'S TREATMENTS

Impact on Discovery

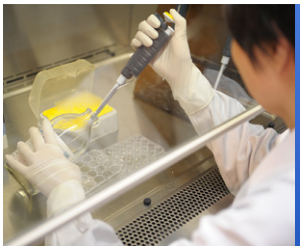
PROGRESS IN THE PIPELINE

A number of advances in the discovery stages of the drug development pipeline took place over the course of 2016. Thanks to ongoing collaboration among our research partners, more drug candidates advanced to IND-enabling studies in 2016 than in the previous five years combined.

This includes two new compounds that advanced into preclinical development: TBAJ-587 (a diarylquinoline), which was discovered in collaboration with Janssen and Auckland Cancer Society Research Center, and TBI-223 (an oxazolidinone), which was discovered with the Institute of Materia Medica. In partnership with Eli Lilly, TB Alliance has also progressed the TBA-7371 compound. All three of these compounds are active against drug resistant strains of TB, and TBA-7371, which inhibits part of TB's cell wall biosynthesis, has a completely novel mode of action against TB.

Additional work on other compounds continued. Collaborations with pharmaceutical partners Sanofi and GlaxoSmithKline are poised to deliver more compounds into the preclinical development phase in 2017.

Over the past year, based on success in the discovery pipeline, TB Alliance expanded its partnership with the Global Health Innovative Technology Fund, an international non-profit organization based in Japan that fosters industry collaboration in global health. A number of "hits," or promising compounds, were identified as a result of natural-product based screens being carried out in collaboration with OP Bio, Daiichi-Sankyo Novare, HyphaGenesis, and Chugai. Funding from the Indonesia Health Fund has also permitted advancing research into natural products in Indonesia.



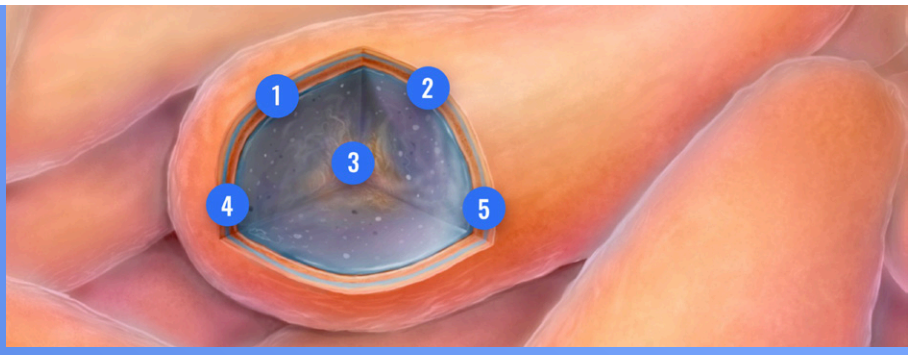
VIEW OUR INTERACTIVE PORTFOLIO

Learn more about TB Alliance's drug development pipeline

HOW WE TARGET TB

FIVE WAYS TO TARGET TB

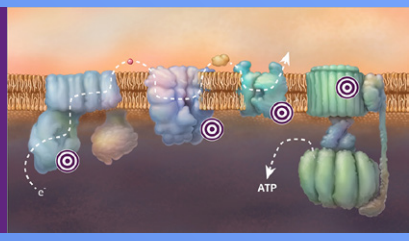
TB Alliance is pursuing five major approaches to targeting TB cells with drugs. These explanatory graphics provide an overview of how TB drugs work at a cellular level. The novel compounds advanced into preclinical development in 2016 target cell wall disruption, central carbon metabolism, and protein synthesis.



PROVEN PATHWAYS

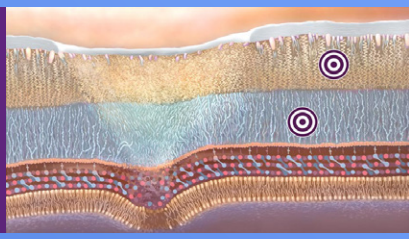
1 ELECTRON TRANSPORT CHAIN

Stop the generation of cell energy so TB bacteria can't grow



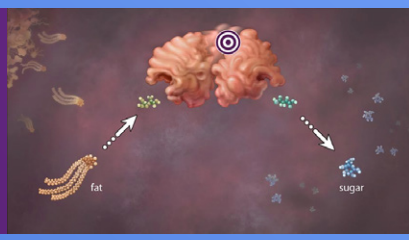
2 CELL WALL DISRUPTION

Weaken cell walls and in the process, destroy TB bacteria



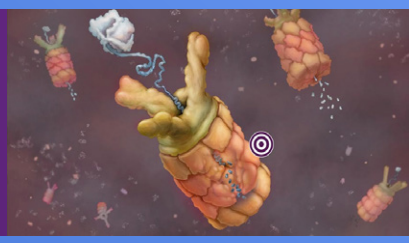
3 CENTRAL CARBON METABOLISM

Starve TB bacteria so it can't grow



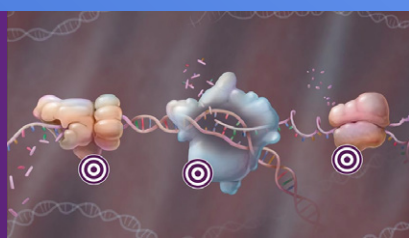
4 PROTEIN DEGRADATION

Poison the cell by inhibiting the ability to eliminate waste



5 PROTEIN SYNTHESIS

Block TB's abiity to make protein necessary for its survival



ACCELERATING DISCOVERY

TB Alliance continued its work with the TB Drug Accelerator Program (TBDA) in 2016, after joining as a full partner in 2015. This program enables signatory organizations to exchange knowledge and establish working relationships in the interest of discovering new TB drugs and treatment regimens. Founded by the Bill & Melinda Gates Foundation, TBDA's ambitious goals include developing five new pre-clinical drug candidates over five years, as well as pursuing their ultimate vision of a one-month, three-drug regimen. This past year's partnership with Eli Lilly to progress TBA-7371 through preclinical development, which arose through TBDA interactions, is just one example of the fruitful relationships that develop through work in this consortium.

A GLOBAL EPIDEMIC

TB is an evolving disease. We need new medicines.

1.8
MILLION PEOPLE

TB is the world's deadliest infectious disease, killing 1.8 million each year

$16.7
TRILLION DOLLARS

MDR-TB could cost the world $16.7 trillion by 2050

6-30
MONTHS

TB therapy lasts from six months to longer than two years

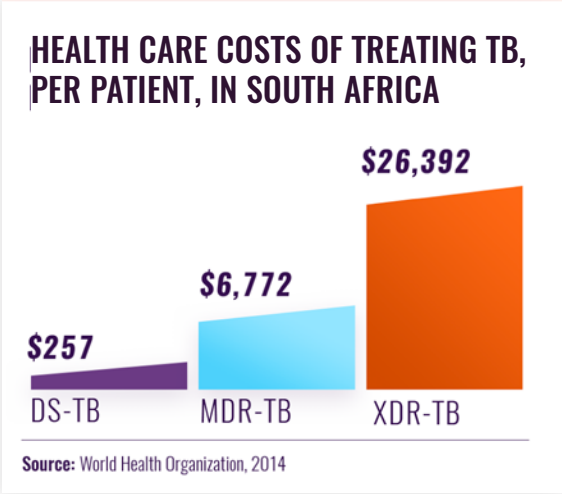
TUBERCULOSIS IS A GLOBAL THREAT

Tuberculosis (TB) is the world's deadliest infectious disease, and a top ten cause of death worldwide.

In its 2016 World TB Report, the World Health Organization estimated that 10.4 million people became sick with TB. Of these, 580,000 cases were drug-resistant. Almost two million people die from TB each year.

TB preys on the vulnerable. Women, children, and people with HIV/AIDS are among those most at risk of this disease, which is transmitted through the air and thrives in weakened immune systems.

TB also propagates a cycle of poverty among those who can least afford it: more than 95% of TB deaths take place in low- and middle-income countries. The high costs of treatment, especially for drug-resistant TB, place an extreme burden on health systems in addition to that on patients and their families.



ANTIMICROBIAL RESISTANCE

In September 2016, the UN General Assembly held its first-ever High-level Meeting on Antimicrobial Resistance (AMR). AMR, the result of microorganisms no longer responding to commonly used antibiotics, has emerged as one of the defining global health issues of our time.

Drug-resistant TB can easily develop in patients when medicine is not properly taken or administered. It can be spread through the air, just like drug-sensitive TB, and is extremely difficult to cure. Estimates from the AMR Review, a report commissioned by the UK government, indicate that almost 30% of deaths related to AMR caused by drug-resistant TB.

770,000

Along with improved diagnostics, new TB treatments could save 770,000 lives over the next 10 years.

Source: AMR Review

NEW TREATMENT REGIMENS URGENTLY NEEDED

Today's prevailing TB drugs, developed half a century ago, aren't working the way they need to. For those with the more common form of "drug sensitive" TB, the shortest available treatment — a best case scenario — consists of daily pills for six months.

For those with multiple forms of drug-resistant TB, the following is the treatment reality: nine months to two years of a dozen or more pills per day, along with six months of daily injections. And for those unfortunate enough to have extensively resistant TB, even if they take every one of those 20,000 toxic pills and hundreds of injections, they will still have less than a one in three chance of survival. In some studies, that number is as low as 16%.

This is what one day of treatment looks like:

XDR-TB

28%

Survival rate with treatment

MDR-TB

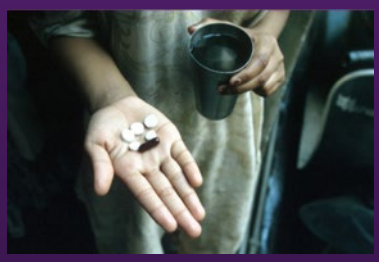
51%

Survival rate with treatment

TB

10.4M

become sick with TB each year



In order to bring the TB epidemic to an end, patients will need better options than these long, toxic, and expensive regimens. TB Alliance is developing better treatment regimens that will be adopted, available, and affordable around the world. Our work to develop improved formulations of medicine for childhood TB is already making an impact in countries like Kenya, and late-stage clinical trials show the promise of shorter, safer, and more effective cures for TB than any currently-available treatment.

By collaborating with donors, research partners, governments, civil society organizations, and others, we are advancing tomorrow's treatments for all.

Learn more about the TB epidemic

JOINING FORCES

COLLABORATING WITH PARTNERS

As a product development partnership, TB Alliance works with a wide variety of partners to advance TB drug development in the most efficient way possible.

We depend on the generous support of our donors to develop and introduce the TB regimens that will impact the epidemic. In addition to private organizations like the Bill and Melinda Gates Foundation and the Indonesia Health Fund, national governments play a major role in funding TB Alliance's work.

Over the past year, the government of Germany announced a five year grant in support of developing new TB treatments. Managed by Germany's Federal Ministry of Education and Research (BMBF) and facilitated by the KfW development bank, this investment is part of a new wave of support directed to product development partnerships to fight neglected diseases like TB.

Additional government sponsors of TB Alliance include the Australian Government (DFAT), Japan's Global Health Innovative Technology Fund (GHIT), Irish Aid, the Netherlands Ministry of Foreign Affairs, UK Aid, and three U.S. government institutions: the National Institute of Allergy and Infectious Disease, United States Agency for International Development, and the United States Food and Drug Administration. UNITAID provided major support for our pediatric program.

TB alliance relies on strong private sector partnership, including from pharmaceutical companies, to develop the next generation of TB medicines — especially in the discovery phase. Historically, for every dollar spent, TB Alliance has leveraged an additional $0.68 from in-kind partner support.

TB Alliance is grateful for the ongoing support of our donor organizations, as well as growing support from private donations, and looks forward to leveraging these investments to further advance the TB drug development pipeline.

PARTNERSHIP WITH MSF

TB Alliance has provided pretomanid, a drug in the final stages of clinical development, as well as its drug development expertise as a partner on a clinical trial launched by Médecins Sans Frontières/ Doctors Without Borders (MSF).

The study, TB PRACTECAL, a composite Phase II-III trial which will run in three countries, will examine the effectiveness of multiple regimens based on two new classes of tuberculosis (TB) drugs that TB Alliance has been testing in separate trials.

By working alongside partners like MSF on clinical trials, TB is enabling further study of regimens that include promising new TB medicines like pretomanid.

INNOVATIVE COLLABORATION: PEPSICO

In October 2016, TB Alliance and PepsiCo announced a new partnership to explore ways to improve the palatability of TB drugs, which are often bitter-tasting and can be difficult to administer to children.

In the initial stages of this collaboration, TB Alliance asked PepsiCo to evaluate 17 existing TB drugs, which PepsiCo then ran through their proprietary flavor-mapping platform. This work is made freely available to TB Alliance for the purposes of improving drug development and treatment. The results of this study will lead to advice on how to formulate these drugs in a more palatable way. Ultimately, this novel partnership seeks to leverage cutting-edge taste science to eliminate poor palatability — a key obstacle in TB treatment for children and other vulnerable populations.

Dr. Mehmood Khan, Vice Chairman and Chief Scientific Officer, Global Research and Development, for PepsiCo, discusses the importance of its collaboration with TB Alliance and the imperative of improving the palatability of childhood TB medicines.

"It's just lovely to think of the fact that children who might otherwise have died or children who might otherwise have gone through months and months of the most painful and often nauseating responses to pills they never wanted to take, that they'll now adjust to a medicine which works."

—Stephen Lewis, co-founder of AIDS-Free World

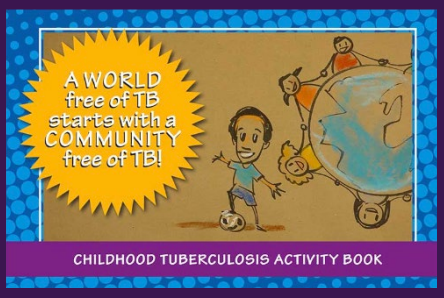
WORLD TB DAY 2016 GALLERY

SCIENTIFIC SYMPOSIUM,
2016 UNION CONFERENCE, LIVERPOOL, UK

ENGAGING COMMUNITIES

Informed and engaged communities make the development of new TB medicines possible. TB Alliance actively supports a robust community engagement (CE) program, which provides grants to research sites to implement strategies which strengthen relationships with community stakeholders and work to inform and solicit input into clinical trials from communities where the research is taking place. In 2016, over 21 CE programs in six countries were provided grants, guidance and technical assistance to develop site-level CE strategies and aid in the work carried out by Community Advisory Boards. Small grants were also issued to support 30 community events in 9 countries to mark World TB Day with screenings and awareness-raising events.

TB Alliance has been promoting the work in CE throughout the year on its Facebook page. One special highlight included an event that took place in May 2016. TB Alliance partnered with the Western Cape Education Department in South Africa to launch an instructional toolkit for teachers and an activity book for children to foster TB literacy in schools. The materials were provided to 24 schools in South Africa over the course of a two-week roll-out. The roll-out was conducted with partners KickTB&HIV and the South African Tuberculosis Vaccine Initiative (SATVI), which provided soccer-based TB awareness activities and educational materials, reaching a total of 17,000 children.



17,000

CHILDREN REACHED

Dowload the complete activity book

INDONESIA HEALTH FUND SUPPORTS CAPACITY BUILDING AND RESEARCH

TB Alliance has received funding from the Indonesia Health Fund to coordinate efforts to build capacity to advance TB research in Indonesia. This includes developing clinical trial sites to conduct TB drug studies, as well advancing early research. With Indonesia being one of the highest TB burden countries globally, this is an exciting opportunity to work with partners in the country to improve TB treatment. TB Alliance is also involved in efforts to improve knowledge about TB disease and research in affected communities in Indonesia.

Global network of partners

TB Alliance is indebted to its partners, especially all participants in our clinical trials, for the successes of 2016.

MOVING CLOSER TO A NEW CURE

Promising Trial Results Point to an Emerging Treatment Paradigm

TREATMENT FOR EVERY PERSON WITH TB

In 2016, TB Alliance realized significant progress in advancing new drug regimens that could significantly impact the TB pandemic. Results from the NC-005 trial and interim results from the Nix-TB trial point to the possibility of a new treatment paradigm where countries could use just two short, simple regimens to treat all people with TB, no matter their resistance profile.

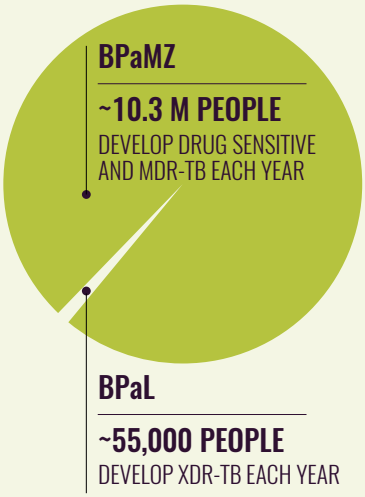
These regimens share two powerful new drugs — bedaquiline (B) and pretomanid (Pa), which TB Alliance began studying in combination in 2012. When B and Pa are paired with moxifloxacin (M) and pyrazinamide (Z) (BPaMZ), results show the regimen has promise to be a common therapy for virtually all patients with drug-sensitive TB and MDR-TB — which comprise the vast majority of TB patients. When bedaquiline and pretomanid are paired with linezolid (L) (BPaL), it creates a closely related treatment for the minority of patients who have the most deadly and difficult to treat TB, XDR-TB.

These two regimens have the potential to transform the treatment landscape. Both BPaMZ and BPaL can be maximally implemented with existing diagnostics, and countries might only need to stock a few oral drugs to treat all types of TB in treatment regimens of 4-6 months. That would be a major improvement from today, where countries devise regimens from more than 20 drugs and injections, which then must be taken for 6-24 months or longer, and, in drug-resistant TB, produce poor — if not dire — outcomes.

Results from the NC-005 and Nix-TB trials were presented at the 47th Union World Conference on Lung Health and at the 2017 Conference on Retroviruses and Opportunistic Infections (CROI).

Drug resistant TB is on the rise. New drugs are urgently needed.

Two Regimens for ALL TB



The BPaMZ regimen is poised to advance

In 2016, TB Alliance reported the positive results of the NC-005 clinical trial. The trial examined drug combinations in patients with drug-sensitive TB and MDR-TB at 10 sites in Uganda, South Africa, and Tanzania. This Phase 2b study tested two different regimens of bedaquiline, pretomanid, and pyrazinamide (BPaZ), and in patients with MDR-TB, those three drugs with moxifloxacin (BPaMZ). The trial was initially launched in October 2014.

The patients in the trial who received a regimen consisting of all four drugs (BPaMZ) saw the quickest reduction in the amount of TB in their sputum. At the end of two months, MDR-TB trial participants cleared TB bacteria up to 3.5 times as quickly as the standard TB treatment regimen had done in drug-sensitive TB patients. In fact, more than three-fourths of patients taking BPaMZ were clear of TB bacteria after this initial two-month treatment (a range of 78–96% depending on whether their TB was fully sensitive to three or all four drugs in the regimen), compared with just 51% taking the standard first-line treatment.

The study also showed that it was possible to simplify the dosing of bedaquiline. Currently, bedaquiline is available in some countries with a dosing scheme of 400mg daily for two weeks, followed by 200mg three times a week for the remainder of a patient's treatment. This makes it difficult to combine bedaquiline into a fixed dose combination. The study found that a daily dose of bedaquiline (200 mg) is at least as active and safe as the labelled dose over a two-month time frame. This will allow for both simpler daily dosing with the regimen as well as incorporation into a fixed dose combination.

If successful in future trials, the BPaMZ regimen could offer a marked improvement over today's prevailing treatment regimens. The BPaMZ regimen could help rationalize and unify TB treatment by offering countries a single, 4-6 month, injection-free regimen that could treat the vast majority (estimated at approximately 99%) of patients. The regimen could be maximally implemented with diagnostics that are already available.

That would represent a major advance from today's current MDR-TB treatment which includes daily injections for six months and more than 14,000 pills over the course of 9 months to two years or even longer. Despite this arduous treatment, the survival rate of those who are able to access the current MDR-TB treatment is only about 50%.

Today, more than one in four deaths caused by antimicrobial resistance are attributed to drug-resistant tuberculosis. The utility and urgency of one simple regimen to treat the majority of patients is already apparent. As the problem of drug resistance continues to grow, improved regimens are an imperative, not only in terms of the financial costs and burden on the healthcare sector, but also the moral imperative to save lives.

Additional research is now being planned and funding is being sought to further advance the BPaMZ regimen.

Thanks to the sites that participated in the NC-005 trial

Thusong Clinic
Johannesberg, South Africa

University of Cape Town Lung Institute (Pty) Ltd
Cape Town, South Africa

Task Applied Science
Cape Town, South Africa

NIMR- Mbeya Medical Research Programme
Mbeya, Tanzania

Ifakara Health Institute
Bagamoyo, Tanzania

The Aurum institute: Tembisa Hospital
Tembisa, South Africa

Uganda Case Western Reserve University Research Collaboration
Kampala, Uganda

CHRU Themba Lethu Clinic
Johannesburg, South Africa

THINK: Tuberculosis & HIV Investigative Network of KwaZulu-Natal
Durban, South Africa

Klerksdorp Tshepong Hospital
Klerksdorp, South Africa

Redirecting Resources for Impact

The promising results of the NC-005 trial and the BPaMZ regimen have compelled TB Alliance to revise its clinical trial plans and redirect its resources to advancing a regimen that has the most potential for impact. As a result, TB Alliance announced in December 2016 that the STAND trial, which is testing the PaMZ regimen, would not re-open enrollment to new patients.

While both the BPaMZ and PaMZ regimens show potential to improve treatment, results show that BPaMZ could improve treatment for significantly more patients, including those with drug-sensitive TB and virtually all patients with MDR-TB, and appears to have greater potential than PaMZ to shorten treatment. Of the 284 patients enrolled in the STAND trial, all have now completed treatment and the initial six-month follow up period. TB Alliance will continue to follow all the patients in the trial for two years as per the original study design. All the associated data will be collected and analyzed, and we will report findings from the trial.

THE NIX-TB TRIAL: PROMISING TREATMENT FOR XDR-TB

Stakeholders Speak about Nix-TB

"The first couple of patients, we wondered is it going to hold? Are they going to stay culture negative? ...and then we just realized, this is what these drugs do. They cure people."

— Dr. Pauline Howell, Sizwe Tropical Diseases Hospital

Testing the BPaL regimen

Today, less than 1 in 3 people survive XDR-TB — and those dismal statistics reflect only those who are able to access treatment. XDR-TB therapy can consist of six months of daily injections alongside two years or more of a daily drug cocktail consisting of a dozen pills or more. These regimens — really, last-ditch salvage treatments — are often accompanied by debilitating side-effects like deafness and psychosis. However, interim results from the Nix-TB (New Investigational Drugs for XDR-TB) trial show the exciting potential to markedly transform treatment of XDR-TB into a treatable and curable disease.

Nix-TB tests a three-drug regimen consisting of bedaquiline, pretomanid, and linezolid (known together as BPaL). Early data from the Nix-TB trials indicate the potential to treat XDR-TB in just six months with a dramatically simpler, safer, and more effective regimen. By the end of 2016, the trial had admitted 65 participants into two trial sites in South Africa, Sizwe Hospital in Johannesburg and Brooklyn Chest Hospital in Cape Town. To date, 34 patients have successfully completed the six-month course of treatment and six months of follow up. Patients will continue to be closely monitored for two years after completing their BPaL regimen. The Nix-TB trial was launched in May 2015. An additional study on early bactericidal activity caused by linezolid, which is linked to toxicity, helped to improved understanding of the drug and will inform future testing of the BPaL regimen.

Building on the promising interim results of the BPaL regimen in Nix-TB, TB Alliance is working to advance this treatment as quickly as possible. The organization expects to launch the ZeNix trial in late 2017. This clinical trial will seek to optimize the use of linezolid in the regimen, including determining the best dose and treatment duration needed to ensure safe, effective treatment while minimizing side-effects. The ZeNix trial is expected to be conducted across 10 trial sites in South Africa, Georgia, Belarus, and Russia. Patients will continue to be enrolled in the Nix-TB trial until the ZeNix trial can be opened.

At the same time, TB Alliance is now planning for the development of a patient access program for the BPaL regimen, working with partners to develop a framework in which patients with urgent medical needs are able to access this ground-breaking treatment prior to regulatory registration. If funding can be secured, TB Alliance will be the first product development partnership to offer such a program.