Taking a STAND Against TB

New Trial Aims to Revolutionize TB Treatment

About STAND

The STAND (Shortening Treatments by Advancing Novel Drugs) trial is a major step in the development of highly impactful novel TB treatments. It is the first Phase 3 registration trial testing a drug regimen (PaMZ) for use against both TB and multidrug-resistant TB (MDR-TB). Conducted by TB Alliance with partners around the world, STAND will be a global endeavor, slated to enroll more than 1500 patients in more than 50 sites in 10 countries. If PaMZ performs successfully in the STAND trial, it will proceed to global registration and made available to the people who need it.

About PaMZ

The combination treatment being tested in the STAND trial is known as PaMZ. This regimen consists of two new drug candidates, PA-824 and moxifloxacin, and pyrazinamide, which is part of the current first-line treatment.

The PaMZ regimen shows promise to:

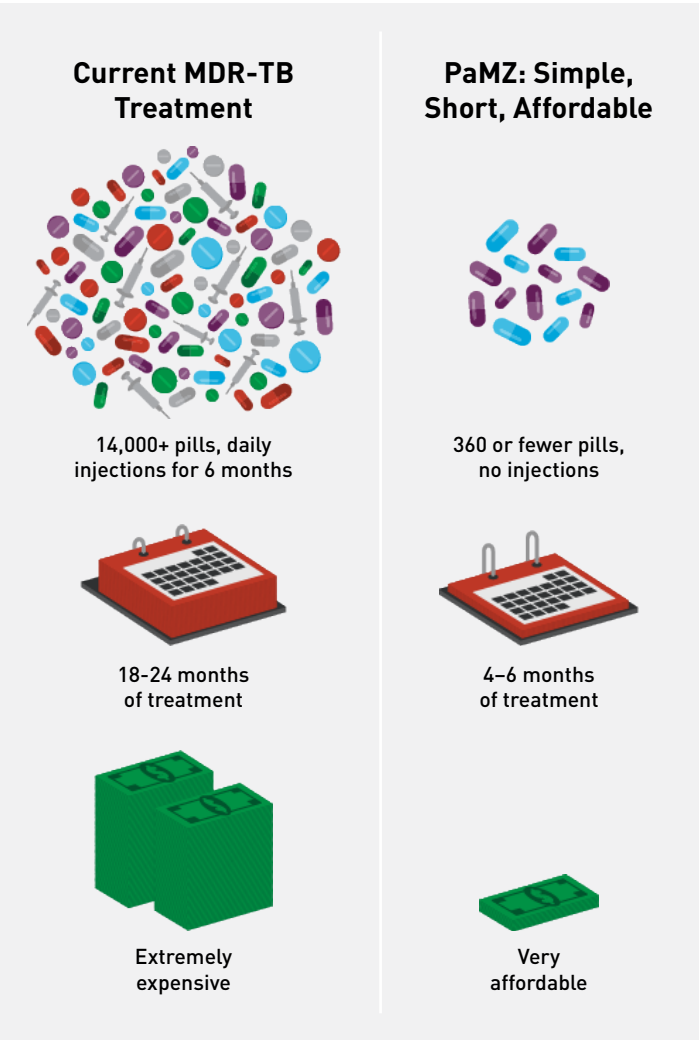
- Treat both TB and some forms of MDR-TB, enabling scale-up of treatment
- Shorten the treatment time of both TB and especially MDR-TB
- Simplify treatment, eliminating 97% of the pills and all injections needed to complete MDR-TB therapy
- Avoid interactions with antiretroviral drugs, improving treatment for the millions of HIV-TB co-infected patients
- Drastically reduce the cost of MDR-TB treatment

New TB Treatments Are Needed

Tuberculosis is a global pandemic, killing 1.4 million each year. It is second only to HIV as the leading infectious killer of adults worldwide, a leading killer of women and children, and the leading infectious cause of death among people with HIV/AIDS. The World Health Organization (WHO) estimates that two billion people are infected with the bacillus that causes the disease.

Today's TB drug regimen takes too long to cure, is too complicated to administer, and can be toxic. As a result, many patients do not or cannot complete their treatment, which leads to the development of deadlier drug-resistant strains, which can then be spread directly. Despite the flaws with and growing resistance to current TB treatments, no new TB drugs have been developed in nearly 50 years, and despite some recent advances in MDR-TB therapy, its treatment remains complex, lengthy and prohibitively expensive for most patients and high-burden countries. Even when treated along WHO guidelines, more than one in three MDR-TB patients don't achieve cure.

Shorter, simpler and novel TB treatments are needed to successfully combat both TB and MDR-TB.

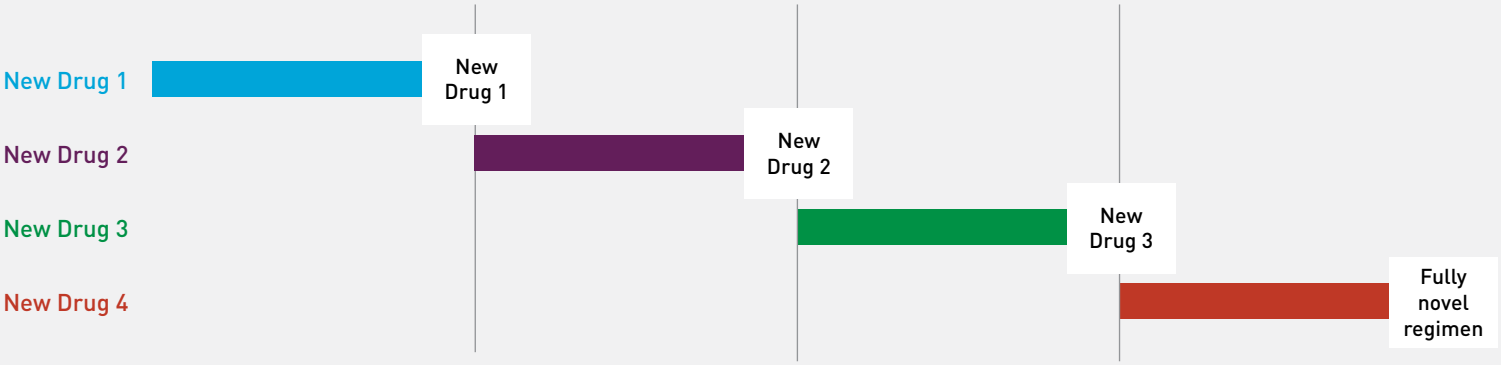


Speeding the Pace of Innovation

STAND doesn't only represent the hope of new TB cures, but also the promise of an innovative scientific approach to developing new products. Since the 1950s, researchers have known that TB must be treated with a combination of multiple drugs to prevent the development of drug resistance. Traditionally, when developing a new drug, researchers would just add on or replace a single drug within the existing standard treatment. Each of these trials could last six years or longer, which means that a novel TB regimen could take decades to develop using this model.

In 2010, TB Alliance began developing PaMZ using a new model that would allow multiple new drugs to be developed at once – making a combination of drugs, and not a single drug, the basis for innovation. This pathway could reduce the time needed to develop a completely novel TB treatment regimen by as much as 75 percent. If the STAND trial is successful, it will mark the first time a new TB drug regimen is developed and registered using this innovative design.

Traditional Drug Development Paradigm



TB Alliance's Combination Development Paradigm

Some regimens in development like PaMZ only consist of three drugs.

TB Alliance operates with the support of the Bill & Melinda Gates Foundation, AIDS Clinical Trial Group, UK aid, Irish Aid, UNITAID, the United States Agency for International Development (USAID), Australian Department of Foreign Affairs and Trade (DFAT), European Commission, Global Health Innovative Technology (GHIT) Fund, National Institute Of Allergy And Infectious Diseases (NIAID), and the United States Food and Drug Administration (FDA).
For more information on TB drug development and TB Alliance, please visit www.tballiance.org.