

Accelerating Development of Essential New Tools to End TB

The UN Sustainable Development Goals aim to end the tuberculosis (TB) epidemic by 2030. To address growing drug resistance and meet this global target, more effective drugs, diagnostics and vaccines are urgently needed. The September 26 UN High-Level Meeting (HLM) on TB is a critical opportunity to strengthen the global response to TB by taking clear and decisive action to support the development of new tools for TB.

Why we need new tools

TB is the world's deadliest infectious disease and it is evolving

10.4 million people became sick from TB and **1.7 million** people lost their lives to TB in 2016 alone.

If not addressed, multidrug-resistant TB (MDR-TB) could cause **2.5 million deaths per year** and cost the global economy as much as **US\$16.7 trillion by 2050**.

Existing tools are not sufficient to meet global targets to end TB. **New vaccines, drugs, and diagnostics will be required to end TB by 2030.**

The following commitments must be prioritized by Heads of State and Governments to accelerate research and development of the new tools that are urgently needed to end TB.

Accelerate development of essential new tools to end TB

- Create a research-enabling environment that streamlines and expedites innovation and promotes collaboration across UN member states in order to introduce new tools to prevent, diagnose and treat TB in all its forms, including:
 - (i) A 2-month or less oral cure for TB and its drug resistant forms before 2028
 - (ii) One or more new or repurposed vaccines ready to enter the registration process for global use by 2025
 - (iii) Affordable point-of-care TB diagnostics that can identify TB disease and drug resistance, as well as tests to detect TB infections
- Acknowledge that TB innovation is a shared responsibility and ensure that all R&D efforts are needs-driven, evidence-based and guided by principles of affordability, efficiency, equity and collaboration.

Invest the funds necessary to end TB

- Increase funding for TB research to close the US\$1.3 billion annual funding gap, for example, through each member state spending up to or beyond 0.1% of its Gross Domestic Expenditure on Research and Development (GERD) on TB research; and implement long-term funding strategies to ensure the sustainability of research progress and pipelines.



NEW VACCINES

- **Vaccines are the most successful and effective public health interventions to reduce** and even eradicate life threatening infectious diseases, but the only licensed vaccine to prevent TB, BCG, is unreliable in preventing TB in adolescent and adult populations – those most at risk for getting sick with TB and transmitting it to others.
- An effective and affordable **TB vaccine** suitable for use in all at-risk populations and capable of breaking the cycle of transmission **is essential for ending the epidemic.**
- A new effective **TB vaccine will** reduce the need for antibiotics and **help curb the rise of antimicrobial resistance.**



NEW DIAGNOSTICS

Access to accurate and rapid diagnosis is often limited in places that bear the highest burden of TB, leading to delayed treatment and further spread of the disease. We need:

- An **easy-to-use, low-cost, non-sputum-based rapid test** for diagnosing active TB that can be deployed in active case finding strategies or used in primary healthcare facilities.
- **Rapid drug resistance tests** that can determine response to critical drugs to direct patients to appropriate treatments and safeguard medicines against antimicrobial resistance.
- An **incipient TB test** to identify individuals at high risk of progression from latent TB infection to active disease and enable targeted preventive treatment.



NEW DRUGS

- **Treatment for TB is long, complicated, often toxic and expensive;** drug resistance to currently available antibiotics is growing.
- Treating drug-resistant TB is especially challenging, with **low success rates** even after years of treatment including **painful daily injections and a high risk of serious side effects.**
- **New, shorter, simpler, safer and more effective therapeutic drug combinations (or “regimens”) are urgently needed to achieve TB elimination.** Researchers are seeking to develop a sustainable pipeline of novel drug regimens that can effectively treat every person with TB.

We have made progress in developing new tools

- Fifteen years ago, there was only one vaccine candidate in the clinical trial pipeline. Today, there are 14, with several more in preclinical development; results from recent clinical trials demonstrate unprecedented progress and offer a unique opportunity for the field to learn, grow and increase momentum.
- The Xpert MTB/RIF test can detect TB and rifampicin resistance in decentralized settings and has reduced the time to receive test results from months to hours. Biomarkers have been identified that make a point-of-care triage test possible, and drug resistance testing could be transformed with sequencing tools.
- In the past five years, two new drugs received accelerated regulatory approval, bedaquiline and delamanid. These are the first new TB drugs in 40 years and they reflect a growing clinical pipeline for drugs which now boasts over a dozen new and repurposed compounds.

But success will require increased and sustained investment in R&D

- The Global Plan to End TB calls for \$9 billion for TB R&D between 2016 and 2020; however, TB research currently receives only one-third of this target annually—and the majority is provided by just five funders.
- Long-term funding strategies are needed to ensure the sustainability of research progress and pipelines, and innovative mechanisms are needed to incentivize private sector engagement in TB R&D.

