

**50** YEARS OF  
GLOBAL HEALTH  
PROGRESS



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# TUBERCULOSIS:

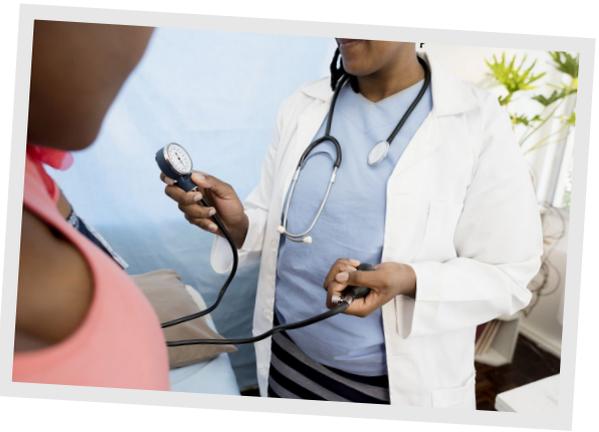
## Thinking beyond traditional models

### TRANSFORMING LIVES

#### PRESENT DAY...

### NISHA'S EXPERIENCE WITH TUBERCULOSIS

Nisha receives treatment for multi-drug resistant TB through newly developed treatments.



#### TWENTY YEARS AGO...

In 1998, Nisha might not have had access to treatment to tackle multi-drug resistant TB and would have expected a shorter life span.

#### IN THE FUTURE...

Nisha hopes for access to treatment for all infected with TB, and research to prevent emergence of future drug-resistant strains.

**Although it has long been preventable and curable, tuberculosis (TB) is the ninth leading cause of death worldwide and the biggest infectious killer. In 2015, 10.4 million cases and 1.8 million deaths occurred from TB. LICs and LMICs see 95% of TB deaths.**

Because TB disproportionately affects vulnerable people, it has not received the same level of attention as other diseases. More women die annually from TB than from all causes of maternal mortality combined. One million children catch TB each year. TB is a strain on fragile healthcare systems: the global TB burden amounts to roughly USD 12 billion annually.

An estimated 53 million lives have been saved through TB diagnosis and treatment between 2000 and 2016. Drugs included in first-line TB treatments were developed more than 30 years ago. Many current treatments for TB require patients to take multiple antibiotics for 24 months or longer, are complicated to administer, and have significant side effects. Many patients stop their drugs before the bacteria have been destroyed, which can further encourage drug resistance.



- 1970: First outbreak of drug-resistant TB in the US.
- 1993: WHO declares TB 'a global emergency' with deaths from TB higher than any previous year.
- 2002: Launch of Global Fund to fight HIV/AIDS, TB, and Malaria.
- 2005: The number of deaths annually from TB peaks worldwide at 2 million.
- 2010: Launch of the Gene Xpert molecular test for TB, a rapid test which is endorsed by WHO and hailed as a major breakthrough.
- 2012: The first approval of a TB drug in 40 years, bedaquiline, unique in that it interferes with the enzyme required by bacteria to replicate.
- 2014: Approval of delamanid, for active multidrug resistant TB, which is added to the WHO's essential medicines list.
- 2015: WHO launches the 'End TB' strategy with the goal of ending the TB epidemic by 2035.
- 2018: (March) Delhi TB Summit; (September) First ever UN High-level meeting on TB in New York City.

## INNOVATIVE RESEARCH MODELS

A central challenge for TB is the lack of competitive markets for medicines in the LMICs where the diseases are most prevalent. In spite of these challenges, R&D-based biopharmaceutical companies are working to eliminate TB through innovative mechanisms, including product development partnerships (PDPs), IP sharing, open innovation, and programs to expand access.

- The **Tres Cantos Open Lab Foundation** allows independent researchers to access GSK facilities, resources, and expertise to advance research into TB.
- The **Novartis Institute for Tropical Disease** is a collaborative research centre, where academic institutions such as the University of Singapore and non-profits such as the TB Alliance work together with Novartis scientists to develop new therapies.
- The **BIO Ventures for Global Health** partnership hub brokered discussions between the Centre for World Health & Medicine (CHWM) and GSK, who both work on MetAP as a drug target for TB. GSK tests identifying inhibitors of MetAP had disappointed and CWHM consequently placed its MetAP inhibitor on hold to avoid repeating experiments, saving money and time.

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## PARTNERING FOR DELIVERY

Methods to prevent, diagnose and treat TB are known. Much harder, yet essential to eradication, is ensuring access to interventions. This is where innovative partnerships are important. Collaborations such as the Stop TB Partnership bring together public, private, and civil society to improve access to treatments, capacity building and policy advocacy.

The inadequacy of current diagnosis has challenged efforts to contain the spread of TB. Janssen has partnered with the non-profit FIND to increase access to molecular diagnostics tools for TB case detection and multi-drug resistant TB (MDR-TB) diagnosis.

### PRE-COMPETITIVE COLLABORATION

The TB Drug Accelerator is a pre-competitive collaboration: the expertise of partner organizations is leveraged to speed the development of medicines. The Bill & Melinda Gates Foundation sponsored consortium of nine pharmaceutical companies and major academic organizations speeds discovery and development of new drug candidates with treatment-shortening potential. Access to compound libraries, collaborative screening and data sharing ensures that members accelerate the most deserving discovery programs and avoid duplication. Coordinating previously siloed research teams and sharing knowledge, capability and resources has led to faster development timelines.

Other resource sharing programs include Eli Lilly's technology transfer program, which provides R&D-based pharmaceutical manufacturers in MDR-TB 'hot spots' with trademarks, technology and know-how.

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## DRUG RESISTANCE

Drug resistance is a growing threat. Each year, there are roughly half a million new cases of MDR-TB, many of them transmissible. Breakthroughs by Johnson & Johnson and Otsuka have recently emerged: two new medicines (bedaquiline and delamanid) have been approved for the treatment of MDR-TB in numerous countries, with both added to the WHO's Essential Medicines List. A priority is getting these new treatments to patients.



A discovery, research and clinical development program spanning two decades led **Johnson & Johnson** to deliver bedaquiline, the first new drug for TB treatment in 40 years.

Steps to promote access include a global distribution agreement through the Stop TB Partnership Global Drug Facility, a safety net donation program through USAID, and equity based tiered pricing in key markets. Johnson & Johnson and Janssen undertake pharmacovigilance and surveillance activities to monitor resistance to bedaquiline and other companion treatments. To date, more than 30,000 patients have been put on bedaquiline in more than 80 countries, including high burden markets such as India, Russia, China and South Africa.



**Otsuka's** FightBack initiative aims to expand access to delamanid and ensure responsible use, as well as to continue R&D efforts into novel MDR-TB treatment options.

As part of the initiative, Otsuka partners with Stop TB Partnership Global Drug Facility to enable LMICs to procure delamanid. The company also participates in the endTB project, led by Médecins Sans Frontières, Partners in Health, and Interactive Research & Development, to evaluate new regimens for the treatment of MDR-TB. Otsuka provided a treatment donation to MSF for the endTB project in order to provide rapid access to patients in urgent need. Otsuka and Mylan also agreed on a license for access to delamanid in LMICs.

## THE PATH TO ERADICATION

*NEW TOOLS ALREADY EXIST THAT SHOULD BE SCALED UP; AND RESEARCH MUST BE DEVELOPED AND ACCELERATED WITH THE NECESSARY FUNDS. IT'S ABOUT RAMPING UP THE RESOURCES TO BRING THEM TO WHERE TB STILL PREVAILS AND KILLS."*

Dr. Francis Varaine,  
Médicins Sans Frontières

## Much remains to be done to meet SDG target 3.3 to end the epidemic of TB by 2030.

Climate change, growing megacities, and conflict present a challenge to meeting elimination targets. Overcrowding, poverty and undernutrition facilitates the spread of TB, which thrives in areas that lack adequate sanitation. It is expected that climate change will cause pathogens to spread to new regions, causing more outbreaks. Given the projected growth in the size of the world's population by 2030, more people will be living in areas at risk of TB, putting further strain on overstretched health systems and budgets. New approaches must deliver interventions in less time, provide flexible funding, and empower communities to administer care when external support is unavailable.

Comorbidity also remains a challenge. HIV patients are at greater risk of TB. There is a need to find new and improved treatments and interventions to tackle this joint disease burden.

Accelerating vaccines development is critical, as is tackling sub-standard drugs, which are at best ineffective, and at worst, can result in death. They also contribute to AMR and drug-resistant infections and reduce patient confidence. Drug resistance presents a major challenge to eradicating TB and as a public health threat. The need for ongoing innovation and a robust pipeline for treatment will become more urgent as strains become resistant to traditional treatments.



### About IFPMA

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees discover, develop, and deliver medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

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### About SustainAbility

SustainAbility is a think tank and strategic advisory firm which for 30 years has worked to inspire and enable business to lead the way to a sustainable economy. SustainAbility works with the life sciences industry on global health, corporate responsibility and sustainability topics.

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