investing in innovation and equitable access to end the tuberculosis epidemic

a global partnership and collaborative initiative

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glossary of terms

Antimicrobial resistance

A process that occurs when bacteria, viruses, fungi, and parasites no longer respond to medicines, making infections harder to treat, and increasing the risk of disease spread and death.

GeneXpert

A rapid diagnostic test that can simultaneously identify mycobacterium tuberculosis and resistance to rifampicin from sputum.

Global health initiatives

Organisations and initiatives that raise and distribute funding for health in lower-income economies. Examples include the Global Fund to Fight AIDS, Tuberculosis and Malaria and GAVI, the Vaccine Alliance.

Gross expenditure on research and development

A country's total expenditure on research and development.

Health equity

The absence of unfair, avoidable or remediable differences in health among population groups, defined by social, economic, demographic or geographic characteristics, where everyone can attain their full potential for health and well-being.

Multidrug-resistant TB

A form of TB disease caused by a strain of mycobacterium tuberculosis complex that is resistant to the two drugs used in first line treatment, rifampicin and isoniazid.

Next generation sequencing

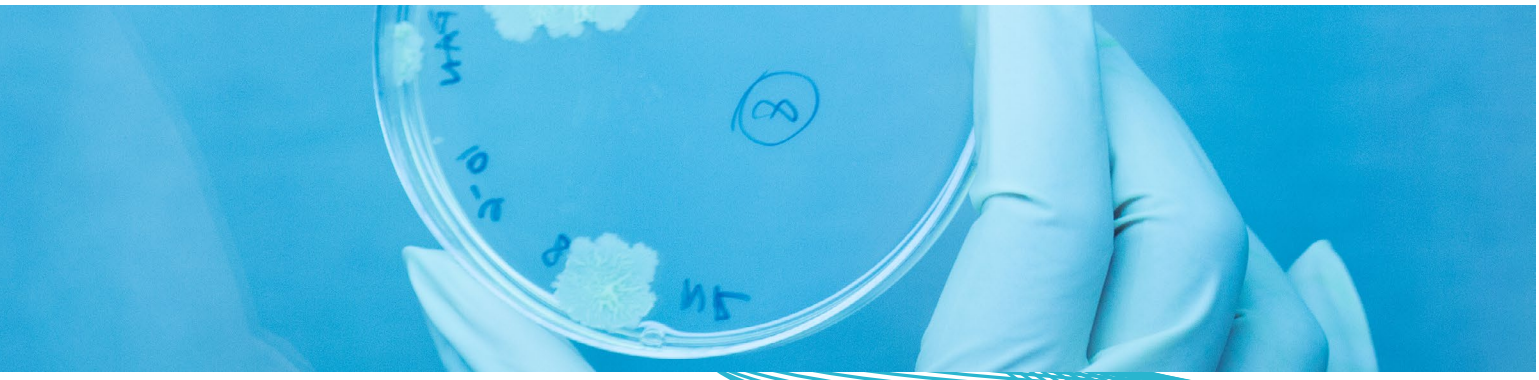
Diagnostic technology that can help detect and characterise TB and drug-resistance through genetic analysis.

Product development partnerships

Non-profit, public-private partnerships that are established to develop and provide access to new health products—such as vaccines, drugs, and therapeutics—for poverty-related and neglected diseases.

Sputum testing

Sputum samples are collected by coughing into a sterile specimen pot and are used to detect the presence of TB bacteria.



TB infection

TB is a bacterial infection spread through inhaling tiny droplets from the coughs or sneezes of an infected person. Persons with latent TB infection do not feel sick and cannot spread TB bacteria to others. People with latent TB have a lifetime risk of developing TB disease, especially if their immune system weakens.

TB disease

TB disease is a contagious, severe infectious disease caused by mycobacterium tuberculosis. It is preventable and curable with proper treatment. TB mainly affects the lungs; however, it can affect any part of the body, including the glands, bones, and nervous system. A person with TB disease can spread the infection to others. On average one untreated individual with TB can spread the infection to 10-15 others per year.

TB preventive treatment

People who are in consistent close proximity and have shared the same airspace with someone with TB disease are at risk of developing TB and need to be protected with TB preventive treatment.

Universal health coverage

All people have access to the full range of quality health services they need, when and where they need them, without financial hardship. It covers the full continuum of essential health services, from health promotion to prevention, treatment, rehabilitation, and palliative care.

Xpert Ultra

A WHO-endorsed molecular diagnostic test for detection of TB and drug-resistance to the drug rifampicin. Xpert Ultra is recommended as a rapid screening assay for people with signs and symptoms of TB.

executive summary

Tuberculosis (TB) is the world's deadliest infectious disease and disproportionately affects people in the prime of their lives, leaving devastation in its wake. TB is not only a physical illness but also a source of stigma, discrimination, financial hardship, isolation, and emotional distress - an unjust and unacceptable reality for millions of people.

Although TB is both preventable and curable, progress toward its elimination has been painfully slow. Despite being the deadliest infectious disease, TB has not received the global attention or sense of urgency afforded to other epidemics such as HIV/AIDS and COVID-19. This neglect is reflected by the ongoing global burden of TB, as well as inadequate political commitment and insufficient financial investment to end one of the world's oldest epidemics. Years of underfunding, driven by apathy, have raised what's at stake. Immediate action is critical. Without it, the human and economic toll will continue to climb.

multifaceted approach

Addressing TB will require a multifaceted approach, given the diverse challenges that are impeding progress towards elimination. In addition to the general complacency towards funding the TB response, there are other financial barriers limiting innovation. Given that the burden of TB falls most heavily on marginalised communities, where it fails to generate profitable returns for investors, investments in research and development are few and far between. This lack of financial incentive contributes to the slow pace of innovation, allowing the disease to spread, and perpetuating cycles of inequality and poverty.

To make real strides in ending TB, we must ensure that no one is left behind. Everyone has the right to benefit from scientific progress and people with TB should be no exception. While there have been advances in treatments and diagnostics, these innovations are not always accessible to all who need them. Building on the progress made in TB research over recent decades requires increased and sustained investment, to improve accessibility to existing tools and develop new ones, including more effective vaccines that offer stronger protection for communities. Now is the time to accelerate research and development efforts. The global TB community is pushing for change, rejecting outdated treatments, demanding access to affordable, fast, and accurate diagnostics, and refusing to accept a 100-year-old vaccine with limited effectiveness. No other disease would tolerate such a lapse - so why should TB?

We must build a TB research and development sector driven by innovation, with incentives designed to prioritise global public health over profit. Regulations must ensure equitable access to life-saving drugs and vaccines, reaching those most in need first. This will require effective collaborations and partnerships that are responsive to the needs of affected communities. Equitable access must be built into the development process as a matter of urgency.

global investment

The world must invest US$5 billion annually in TB research and development to deliver the tools we need to reach the 2030 TB elimination goals. Achieving this is within reach if all countries contribute their fair share. Investing in TB research offers not only financial returns but also strengthens health systems, builds research capacity, improves health outcomes, and enhances global health security for all. We know what needs to be done to end this curable disease. What is required now is sustainable funding and policy reform, backed by strong political will, to bring new innovations to life and ensure that they reach the communities that need them most.

recommendations

1. UN member states must meet their fair share contribution to the global TB response by allocating 0.15% of their national gross expenditure on research and development to TB.

Read more on page 7

2. Donor countries must attach conditions for public funding to ensure equitable access to innovations.

Read more on page 10

3. Donor countries must support the development of regional manufacturing capacities for essential medicines, vaccines, and medical devices in high-burden countries.

Read more on page 10

4. Donor countries must support the ongoing work of Product Development Partnerships to create new tools at lower costs.

Read more on page 11

5. All TB stakeholders must work to integrate TB within existing global and national health agendas, including those for antimicrobial resistance and pandemic preparedness prevention and response.

Read more on page 12

6. All TB stakeholders must leverage global partnerships, increase synergies, and create new alliances with relevant partners, including affected communities.

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7. UN member states must uphold the commitments endorsed in the 2023 Political Declaration of the United Nations High-Level Meeting on TB.

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about tuberculosis

Tuberculosis (TB) is the world's leading infectious disease killer. It has claimed more than a billion lives over the past 200 years.[1] In 2022 alone, TB affected over 10 million people and caused 1.3 million deaths.[2]

In 2012, UN member states committed to eliminating the TB epidemic by 2030 as part of the Sustainable Development Goals.[3] While the world has long been off track from this target, progress was set further back by the COVID-19 pandemic, which diverted critical resources and led to the first increase in TB deaths in over a decade.[4] While a meaningful global recovery in the TB response was reported in 2022, we are still a long way from eliminating this deadly disease.[2]

Image 2. *Source: TB REACH.*

If current trends persist, the world could see 31 million TB deaths by 2050, with an economic cost of US$17.5 trillion – a staggering loss of both human life and potential. However, with substantially expanded financing, the universal implementation of existing tools, and the creation of new ones, TB deaths can be cut by 90% by 2030.[5]

Intensifying efforts to end TB will be crucial to alleviating preventable suffering and addressing emerging challenges, such as drug-resistance. Drug-resistant TB (DR-TB), which resists standard antibiotics, places an even greater burden on health systems and patients with longer, more expensive treatments and suboptimal success rates. As such, DR-TB currently contributes to nearly one-third of global antimicrobial resistance (AMR) related deaths.[6] Investing in TB research and development (R&D) to enable scientific innovation is essential to curbing the spread of disease, ensuring timely and accurate TB care, and mitigating the broader AMR crisis.

Image 1. *Source: FIND.*

We need a robust, multidisciplinary approach supported by sustainable funding to combat TB and its evolving challenges. Strengthening health systems, addressing social determinants of health, and dismantling regulatory barriers are essential steps in this process. But at its core, the TB epidemic is perpetuated by inadequate funding and insufficient political will. Investing in R&D to improve the tools available for the prevention, diagnosis, and treatment of TB is a critical pathway to eradicating this disease. The current reliance on outdated tools is unacceptable - people affected by TB deserve access to modern, effective solutions.

Donor countries must fulfil their moral obligation (and commitments they have made) to contribute their fair share towards TB R&D and work to ensure that everyone has the right to benefit from scientific innovation.[7] With the development and widespread availability of new, more effective tools for preventing, diagnosing, and treating TB, we can move closer to a world free from this disease.

Fatima's story

Fatima, a multidrug-resistant (MDR) TB survivor and advocate from the United Kingdom (UK), faced a harrowing journey beginning in 2017 as a university student. She developed a cough, which later progressed into severe TB symptoms. It took many months, repeated doctor visits, and being hospitalised before Fatima was finally diagnosed with TB. She was started on first-line medications for TB. After a few days, she was called back into hospital and put into an isolation room when it was discovered she had drug-resistant TB. Without proper explanation or support, Fatima learned about her condition through online research.

For the next 50 days, Fatima remained isolated with minimal contact with the medical staff, who avoided direct interaction with her. Her meals were left outside her room on a waste bin. The toxic side effects of her medication led to additional complications and significantly affected her mental health.

Despite enduring a gruelling two and a half years on an outdated MDR-TB regimen, involving thousands of pills and hundreds of injections, Fatima is now a strong advocate speaking out against the stigma associated with TB.[8]

"I would like to, through my story, explain to healthcare professionals and parliamentarians (and people who can make a difference) that we do need the support. TB needs a better and quicker diagnosis. There needs to be more people skills and thoughtfulness towards patients and treat them like human beings".

- Fatima, TB Survivor & Advocate

Image 3.

Source: Results UK, 2024.

challenges in the global tuberculosis response

The persistence of TB is a proxy for inequity and reflects global indifference toward addressing diseases that predominantly affect marginalised communities. Meaningful progress toward TB elimination is restricted by chronic underfunding, inequitable access to essential tools, profit-driven models, a siloed approach to policy development, insufficient collaborative action, and – above all else – a lack of political will.

chronic underfunding

Chronic underfunding for R&D has severely hampered efforts to develop better diagnostics, drugs, and vaccines for TB. Current tools are suboptimal, with diagnostics often failing to detect MDR-TB, long treatment regimens causing severe side effects, and a century-old vaccine providing limited protection beyond childhood.[9] and far between. This lack of financial incentive contributes to the slow pace of innovation, allowing the disease to spread, and perpetuating cycles of inequality and poverty.

While intentions to address this critical funding gap were confirmed at the UN High-Level Meeting (HLM) on TB in 2018, where member states committed to providing US$2 billion annually for TB R&D, this target has never been met.[10] As funding remains low, demand continues to rise. Years of underfinancing, coupled with the impacts of the COVID-19 pandemic, have increased the required funding to US$5 billion annually.[9] At the most recent UN HLM on TB in 2023, a renewed commitment to this new target was made, which will require member states to allocate 0.15% of their gross expenditure on R&D to TB.[7] With just over US$1 billion raised in 2022, there is an urgent need for donor countries, as well as private and philanthropic organisations, to step up their support.[10]

1 recommendation for chronic underfunding

UN member states must meet their fair share contribution to the global TB response by allocating 0.15% of their national gross expenditure on research and development to TB.

table 1: progress towards fair share funding targets in 2022

Fair Share = spending at least 0.1% of overall R&D expenditures on TB R&D

RANK	COUNTRY	2022 FUNDING	FAIR SHARE TARGET	PERCENT OF TARGET MET IN 2022
1	United States	$436,073,634	$444,500,000	98%
2	Germany*	$36,093,374	$99,700,000	36%
3	United Kingdom	$32,682,386	$40,400,000	81%
4	India	$24,162,920	$46,500,000	52%
5	South Korea	$22,853,436	$64,000,000	36%
6	France*	$20,084,103	$55,400,000	36%
7	Australia	$13,894,959	$21,200,000	66%
8	Canada	$13,581,440	$25,300,000	54%
9	Italy*	$10,427,256	$27,500,000	38%
10	Japan	$8,120,185	$154,900,000	5%
11	Spain*	$7,909,472	$20,799,869	38%
12	Sweden*	$5,720,111	$13,700,000	42%
13	Netherlands*	$4,991,442	$15,100,000	33%
14	Switzerland	$4,948,543	$13,400,000	37%
15	Brazil	$4,735,865	$35,000,000	14%
16	South Africa	$4,206,545	$4,600,000	91%
17	Ireland*	$3,269,509	$3,300,000	99%
18	Denmark*	$2,718,640	$7,500,000	36%
19	Belgium*	$2,668,488	$10,900,000	24%
20	Finland*	$2,384,144	$7,100,000	34%
21	New Zealand	$1,397,953	$1,800,000	78%
22	Peru	$1,061,794	$420,000	253%
23	Singapore	$746,036	$8,400,000	9%
24	Malaysia	$738,818	$9,807,000	8%
25	Norway	$688,332	$5,300,000	13%
26	Philippines	$655,254	$700,000	94%

Table includes countries that reported more than $500,000 in TB R&D expenditures to TAG.

* 2022 funding for EU Member States (third column) includes a proportaional share of total TB R&D spending by the European Commission mechanisms (EDCTP, EC, AM | IMI) equal to the member state's "total national contributions" to the general EU budget in fiscal year 2022.

Table 1

Source: Treatment Action Group, 2023[10]

Caption: Progress toward fair share funding targets in 2022. Note that, as of 2023, the fair share has been updated to spending 0.15% of overall R&D expenditure on TB R&D.

table 2: TB vaccine funding compared to COVID-19 and HIV

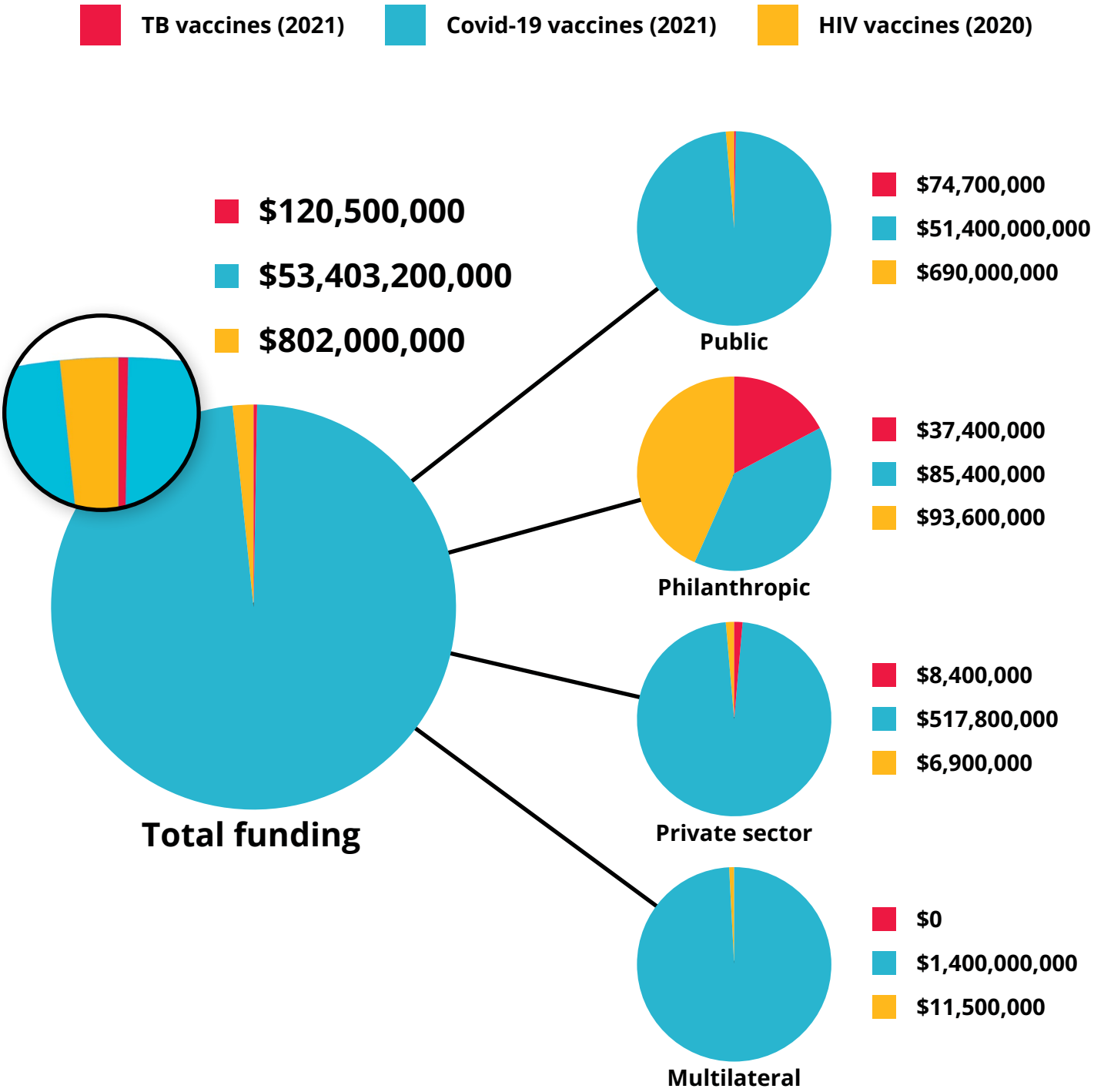


Table 2

Source: StopTB Partnership Working Group on New TB vaccines, 2024[11]

Caption: Analysis from the Stop TB Partnership and the TB Vaccine Advocacy Roadmap shows the disparity in TB R&D funding for vaccine development. The figures clearly show the inequity of financing across the different diseases and reflect the low priority given to TB. The large investments in the COVID-19 vaccine show how high-income economies can mobilise when the disease affects their citizens, further widening the inequality gap at the expense of TB and low-resource countries. The level of investment for COVID-19 in only one year puts into perspective what can be achieved if all sectors work together for the common good. The financing disparity reinforces the discrimination of TB and people affected by TB.

inequitable access to essential tools

Inequitable access to essential tools is a major barrier to addressing the TB epidemic, leaving millions of people with TB without the care they need. Although TB is curable, it requires timely diagnosis and treatment. Of the 10.6 million people who fall ill with TB annually, an estimated 4.2 million are missed by health systems.[12]

Structural and regulatory barriers to accessing diagnostics and care are exacerbating this issue, but they do not have to. Public funding plays a pivotal role in TB R&D, and therefore donors can meaningfully shape the way new tools are distributed by attaching access conditions to such funding. The inequities observed in the distribution of COVID-19 vaccines should serve as a cautionary tale. Governments must act to maximise the public return on public investments by embedding equity-focused criteria into funding agreements. These conditions might include price guarantees to ensure affordability, priority access to the most affected communities, and royalty-free agreements with volume guarantees for high-burden countries. Harmonising registration pathways for medical products will help expedite access to those most in need and promote equitable distribution of innovations as they become available.

3 **recommendation** for inequitable access to essential tools

Donor countries must support the development of regional manufacturing capacities for essential medicines, vaccines, and medical devices in high-burden countries.

2 **recommendation** for inequitable access to essential tools

Donor countries must attach conditions for public funding to ensure equitable access to innovations.

Donor countries can improve access to innovations by supporting regional manufacturing in high-burden countries, allowing these countries to overcome the challenges of importing from the global north. Over-reliance on donor aid can undermine the sustainability and equity of TB control efforts. For example, while Africa shoulders 25% of the world's disease burden -including major infectious diseases like HIV, TB, and malaria - more than 95% of the active pharmaceutical ingredients and 70% of the pharmaceuticals consumed on the continent are imported.[13] This leaves countries vulnerable to price volatility, supply chain disruptions, or unavailability of essential health products, particularly during periods of supply scarcity in the face of surges in regional or global demand or after climate-related shocks or extreme weather events. By investing in local manufacturing capabilities, countries can reduce their dependence on external aid, enhance their capacity to produce and distribute TB tools locally, and improve access for their populations. Initiatives like the African Vaccine Manufacturing Accelerator (AVMA) present significant opportunities to reinforce these efforts. By prioritising technology transfer and capacity-building, AVMA can help strengthen local production and regulatory frameworks, ensuring that R&D in Africa is robust and that the continent can meet its own needs more effectively.[14] This model should be replicated across the continuum of care and in other low-resource settings.

profit-driven models

Profit-driven models have impeded the development and availability of new, affordable TB tools. This is because traditional market incentives fail to spur significant private sector investments in TB. The high cost of existing diagnostics and treatments limits their reach, particularly in low-income regions. This can negatively impact the capacity of resource-limited countries to purchase the tools that their communities need.

4 recommendation for profit-driven models

Donor countries must support the ongoing work of Product Development Partnerships to create new tools at lower costs.

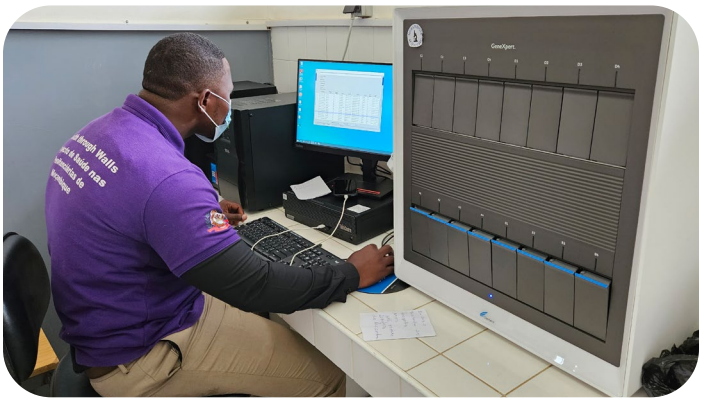


Image 4. *Source: TB REACH*

Caption: GeneXpert machines are used to detect TB, enabling people to start treatment sooner and reduce the risk of transmission. These tools remain out of reach to those most in need. Challenges remain for resource-limited countries in the cost of new diagnostic tools, the consumables and the need for the necessary infrastructure and human resources to implement the new technology – especially in remote areas that don't have a reliable supply of electricity, for example. The individual cost of a GeneXpert test for TB is $7.97 per cartridge, which increases to $14.90 per test for drug-resistant forms of TB.[15] Civil society and humanitarian organisations have been calling for a reduction in the cost of GeneXpert tests for over 10 years so that more people can access tests that can save their lives.[16]

In addition to the tools themselves, countries must have the proper infrastructure and human resources to implement these technologies, which are not always available. It is therefore critical that access and applicability of new tools are considered from the very beginning of the product development process, ensuring that new tools will be accessible and useful in the communities that need them. Product Development Partnerships (PDPs) are working to alleviate the financial burden that countries bear when trying to protect their communities by developing new products that serve communities better, at a lower cost.

PDPs produce new products tailored for individuals grappling with diseases and health threats underserved by traditional markets by building partnerships between the public, private, academic, and philanthropic sectors. In the global health space, PDPs have pioneered treatments, vaccines, diagnostics, vector controls, devices, and various other forms of innovation that have led to significant progress against some of humanity's most enduring and lethal pandemics, including TB.[17]

In disease areas where traditional market incentives fail to spur significant private sector investments, PDPs, along with their funders and collaborators, emerge as pivotal agents of innovation, developing health solutions that would otherwise remain unrealised. This is particularly evident in the case of TB. PDPs minimise product development costs while delivering solutions that offer substantial financial and health returns, making investment in PDPs a sound strategy for partners looking to improve global health, catalyse global development, and uplift vulnerable populations, including women and children.

With adequate financial and political backing, PDPs can sustain their efforts to develop and drive equitable global access to health technologies, potentially saving millions of lives, lifting populations out of poverty, and fortifying global security in the decades ahead.

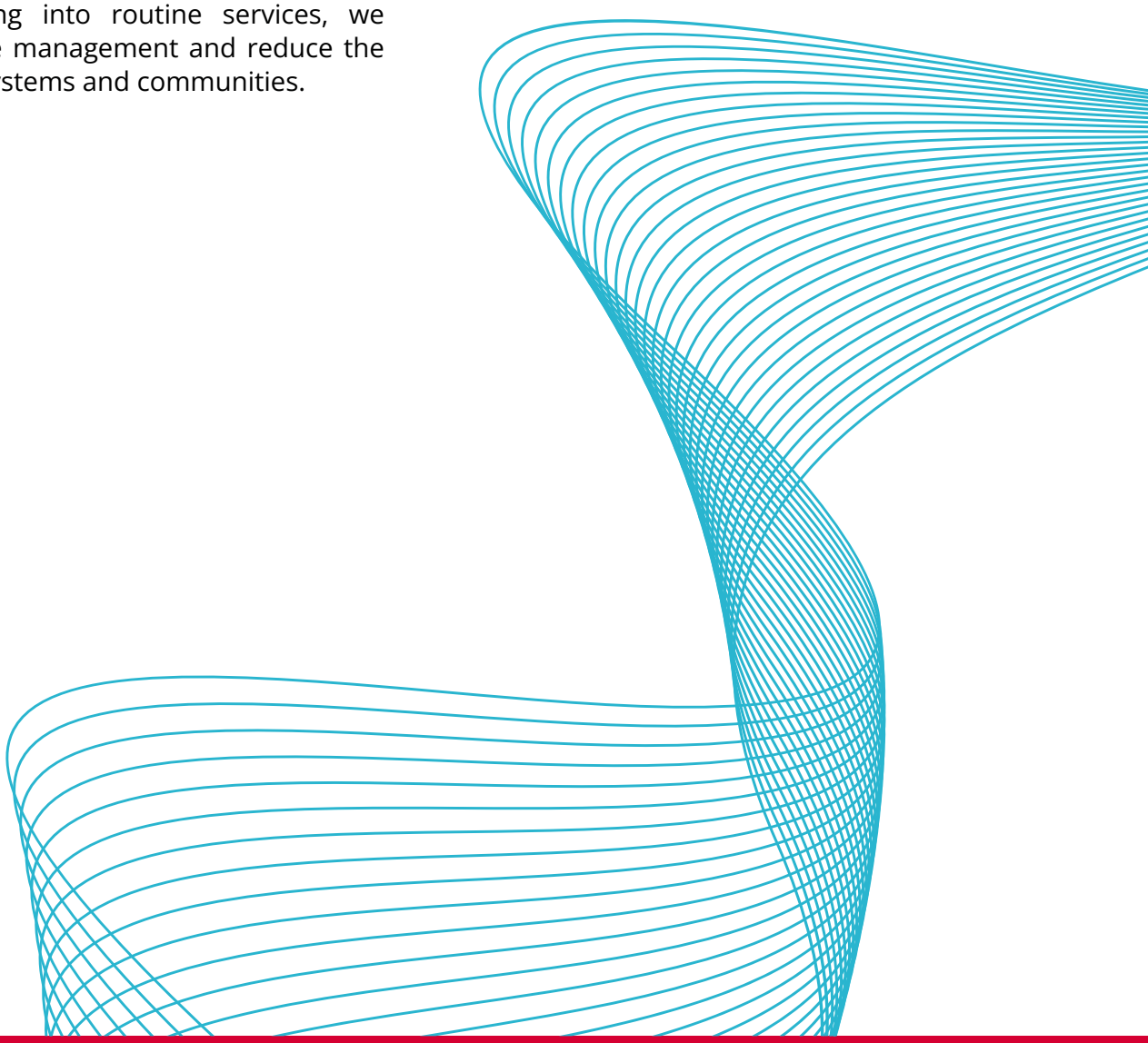
a siloed approach to policy development

A siloed approach to policy development has long hindered progress in global health. Although many underlying determinants of disease – social, structural, physical, and legal – are consistent across various health challenges, much of global health remains compartmentalised, focusing on individual outcomes rather than the shared drivers of widespread suffering.

There is a significant opportunity to adopt a unified strategy, both at national and global levels, to enhance coordination, optimise resource allocation, and bolster the resilience of health systems against multiple diseases. By investing in health system strengthening, advancing universal health coverage at the primary care level, and integrating multi-disease testing into routine services, we can streamline care management and reduce the burden on health systems and communities.

5 **recommendation** for a siloed approach to policy development

All TB stakeholders must work to integrate TB within existing global and national health agendas, including those for antimicrobial resistance and pandemic preparedness prevention and response.



insufficient collaborative action

Insufficient collaborative action amongst TB stakeholders is holding us back from optimising the global TB response. Global health institutions, governments, the private sector, civil society, and communities all play critical roles in addressing TB, but their efforts often lack the coordination needed to maximise impact. The lack of collaboration leads to fragmented efforts where resources are spread thin, priorities are misaligned, and duplication of work occurs. This not only wastes valuable time and money but also undermines the overall effectiveness of TB control efforts.

Meaningful collaborations are forming, particularly between global health institutions (GHIs) with overlapping missions, but there is always more that can be done. A global call for increased collaboration between GHIs was formalised through the establishment of the Lusaka Agenda in 2023.[18]

The Lusaka Agenda provides a foundation for coordinated action for GHIs, and a path towards a joint long-term vision of domestically-financed health systems and universal health coverage that leaves no one behind. Following this initial call for increased collaboration, all TB stakeholders should continue to align with others to maximise impact.

6 **recommendation** for insufficient collaborative action

All TB stakeholders must leverage global partnerships, increase synergies, and create new alliances with relevant partners, including communities.

a lack of political will

A lack of political will is the root of why the world continues to grapple with TB. A curable and preventable disease like TB should not be killing over a million people every single year. If political leaders truly prioritised ending TB, it can be eradicated.

Eliminating TB remains within our reach, but it demands decisive action and accountability from heads of state. UN member states have made explicit commitments to end TB and set specific targets to achieve this goal. However, these targets will only be met through concrete, meaningful actions. It is imperative that UN member states uphold the commitments enshrined in the Political Declaration, reaffirmed at the UN High-Level Meeting on TB in 2023.[7]

7 **recommendation** for a lack of political will

UN member states must uphold the commitments made in the Political Declaration on TB.

Image 5. *Source: TB REACH.*

making the case for investment in research and development

Investing in R&D is a fundamental driver of progress in global health and increased life expectancy. New technologies and innovations have the potential to save lives, improve health outcomes, stimulate economic growth, and strengthen health security worldwide.

substantial return on investment

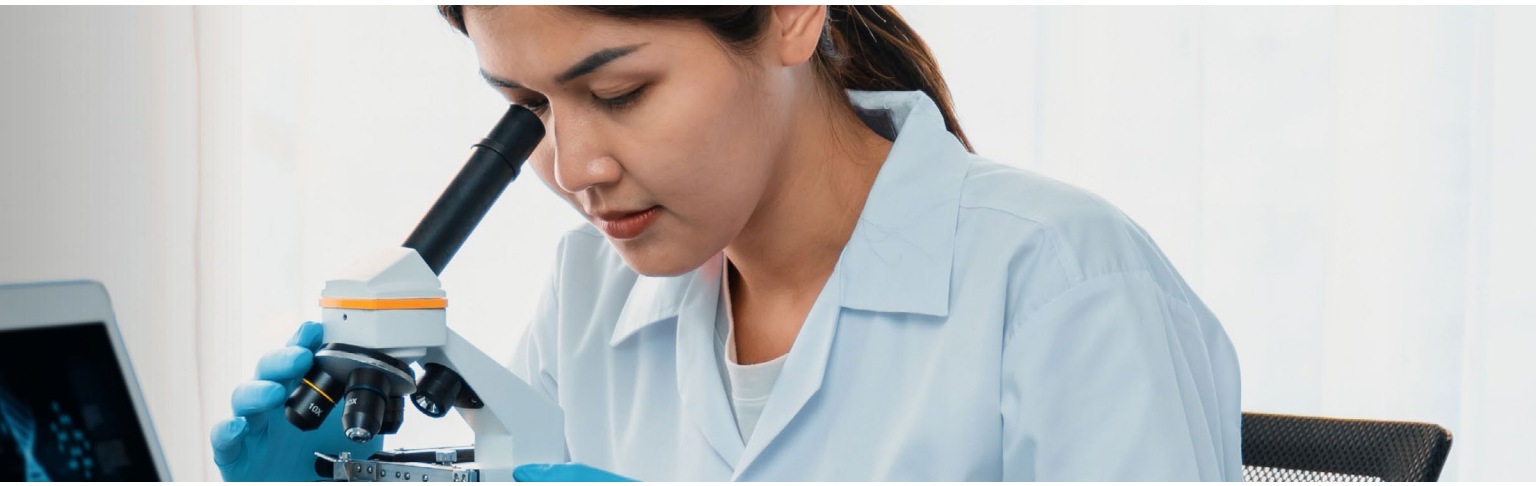
Even when donor countries are not the direct beneficiaries of these innovations, their investments in global health R&D yield substantial returns. These investments build long-term capacity within the global health sector, create jobs, and generate opportunities both inside and outside the research community, creating a multiplier effect. Despite the costs associated with producing products, establishing supply chains, and funding health systems to deliver these products, the benefits far outweigh the costs.

The return on investment in global health R&D is substantial. For every US$1 invested, there is an estimated return of US$405 in broader societal and economic gains.[19] This figure represents the retrospective and prospective impact of products that have come to market over the last 20 years, as well as the future potential of innovations expected to become available by 2040.

For every US$1 invested, there is an estimated return of US$405 in broader societal and economic gains.

strengthening primary healthcare systems

Investment in primary healthcare systems is crucial for achieving universal health coverage and addressing global health threats such as AMR and future pandemics. Primary healthcare systems can also integrate pandemic, prevention, and preparedness response (PPPR) capabilities. The infrastructure required to detect, diagnose, and treat TB are the same systems that can be scaled up to respond to pandemics and emergencies – as was the case during COVID-19. In fact, countries with more efficient TB programs were found to be better able to control COVID-19.[20] Strengthening platforms for detecting respiratory pathogens of pandemic potential will optimise diagnostic networks, improve real-time surveillance systems, and expand the workforce's capability to respond effectively. By integrating PPPR capacities within primary healthcare, all people can be reached, reducing gaps in prevention, diagnosis, treatments, and care, and promoting equity.[22]



addressing the twin threats of TB and AMR

Successfully diagnosing and treating people with TB, and reaching more people with vaccinations, will help prevent the development and spread of DR-TB. TB accounts for one third of all deaths related to drug-resistance and the World Health Organization (WHO) has recently added TB bacteria to its list of drug-resistant bacteria most threatening to human health.[23] There is therefore an urgent need to address AMR within the context of TB control and prevention. In doing so, we can build a foundation for stronger diagnostic systems and treatment coverage to underpin health systems around the world, combat a key driver of the global threat of AMR, and help accelerate progress in addressing it.

TB accounts for one third of all AMR-related deaths

Image 6. *Source: GAVI, 2020.*

strengthening preparedness for future health threats

New vaccine research science, such as messenger RNA technology, can be further advanced to develop vaccines against TB and future pandemics.[22] Using an integrated and systems-based approach that incorporates health system strengthening and capacity-building – including for research and regulation – will help to ensure equitable access to effective quality medicines, vaccines, and diagnostics. This will also ensure effective stewardship of AMR in the progress of achieving universal health coverage.[24] Investments in innovative tools for prevention, diagnosis, and treatment will not only combat TB but also strengthen global health systems, enhancing preparedness for future health crises and promising a healthier, more secure future for all.

key players leading ongoing innovation

The TB R&D ecosystem is a dynamic and diverse network, with funders fueling the essential work of a broad array of partners, including research institutions, universities, multilateral organisations, and PDPs. These collaborative efforts are driving groundbreaking innovations that are already saving lives. The potential of these institutions to significantly influence global TB elimination is vast, but achieving this goal requires increased funding and enhanced coordination. By expanding financial support and fostering greater collaboration among these stakeholders, we can make substantial progress toward eliminating TB.

The following outlines some of the exciting innovations and initiatives currently underway to address the TB epidemic, highlighting the tremendous impact that could be achieved with increased investment and support.

diagnosing the problem

One of the greatest barriers to ending TB is that each year, approximately four million people with TB are missed by health systems and do not get the care they need.[25] Reaching the "missing millions" is imperative to global TB elimination because of the nature of infectious diseases: the more people who are missed by health systems, the greater the risk of disease spread. Accurate and timely diagnoses are crucial, as 5-10% of the 1.8 billion people who are infected with TB bacteria will develop the disease in their lifetime.[2] However, in 2022, only 47% of people with TB were diagnosed using WHO-approved rapid tests, which are essential for detecting DR-TB and initiating early, effective treatment.[25] Many countries still rely on outdated tests that are ineffective at accurately diagnosing drug-resistant strains of TB and are not suitable for children. Diverse partners across the TB ecosystem are working to address this issue and ensure that everyone receives the care they need. The **Stop TB Partnership's TB REACH** initiative, for instance, is an innovative financing mechanism that supports its grantees in ensuring that people in underserved communities can access the care that they need and would otherwise go without.

An estimated 4 million people with TB are missed by health systems every year.

Stop TB Partnership
TB REACH

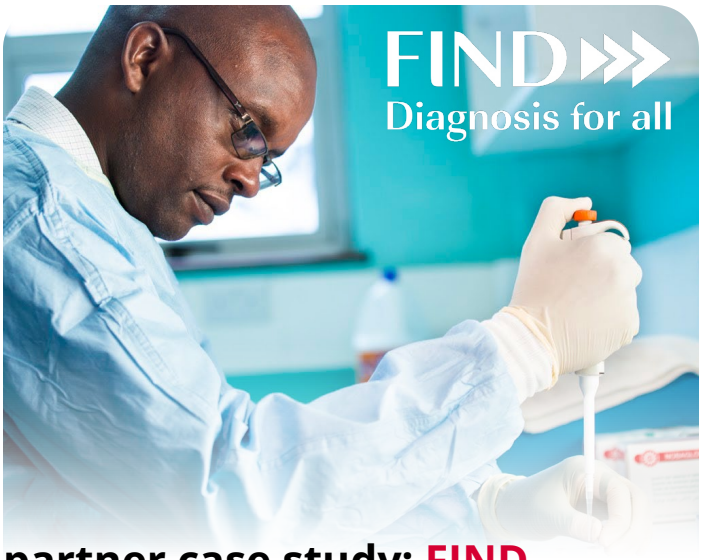
partner case study:
TB REACH

The Stop TB Partnership's TB REACH initiative has been leading the early adoption and integration of innovative technologies like Xpert, ultra-portable X-rays, and artificial intelligence-driven chest X-ray reading for TB detection. These have contributed to the development of new global guidelines and the scaling up of interventions using these technologies, making them a core strategy within national TB programs in high-burden countries. The results: since the program's inception in 2010, TB REACH grantees have screened more than 43 million people for TB, resulting in over three million people being diagnosed and put on treatment. Their work has saved approximately 1.5 million lives, as well as helped to stop TB from spreading within communities most at risk.

Image 7. *Source: TB REACH.*

Another key player in bridging the diagnostic gap for TB and other diseases is **FIND**. As a global non-profit, FIND connects countries and communities, funders, decision-makers, healthcare providers, and developers to ensure equitable access to reliable diagnosis worldwide. FIND's TB strategy focuses on the development of new point-of-care tests and strengthening community-based testing. By increasing test availability where and when needed, FIND aims to reduce the number of people with TB who are missed and improve diagnosis for diseases with similar symptoms, like COVID-19.

Image 8. *Source: FIND.*



partner case study: FIND

In 2020, FIND and its partners developed Truenat MTB, molecular tests to identify TB and detect rifampicin resistance, suited for use at the point-of-care in low-resource primary healthcare settings. These tests matched the performance of Xpert Ultra, the only rapid molecular test at the time, leading to their endorsement by the WHO.[26]

FIND is also exploring innovative diagnostics, such as using tongue swabs for TB detection, especially when sputum samples are not available. This approach, validated by COVID-19 testing, offers a less invasive alternative without the need for additional equipment. Studies are currently underway in several countries across Africa, South Asia and South America to confirm if oral swabs - using the same methods and machines that were used for COVID-19 - can accurately detect TB, with results potentially available in a few hours.

To address critical gaps across different healthcare settings, FIND, as part of its DriveDx4TB project funded by Unitaid and supported by TB REACH, will support the development of:[27]

- Third-generation lipoarabinomannan-based rapid tests: highly sensitive urine test for fast and simple TB diagnosis at point-of-care.
- Portable molecular diagnostics: rapid point-of-care tests using non-sputum-based samples.
- Low complexity nucleic acid amplification tests: broader drug susceptibility testing and faster DR-TB detection.

In another important progressive move, the WHO now recommends targeted next-generation sequencing (NGS) for the detection of DR-TB, supported by FIND data and funded by Unitaid.[28] Targeted NGS can predict drug-resistance within a few days by examining mutations in the genes of TB bacteria and can help tailor effective drug regimens. This significantly speeds up diagnosis in comparison to traditional culture-based tests, which take up to eight weeks to recognise resistance. Targeted NGS can identify resistance to multiple drugs simultaneously and can be quickly updated to incorporate new resistance profiles as they emerge which is vital in staying ahead of TB mutations. Targeted NGS offers a comprehensive prediction of drug-resistance and is critical for implementing new, shorter DR-TB regimens, including those with the drug bedaquiline, which other rapid diagnostic platforms cannot identify.

developing better treatments

Drug-resistant forms of TB pose significant treatment challenges and have historically exhibited high mortality rates despite therapy. Treatment regimens have long required people to take drugs for nine to 18 months, often involving painful injections and severe side effects. The success rate of these treatments is less than 60 percent[29] – a disheartening figure for the nearly half a million people who develop DR-TB annually.[12]

TB Alliance is a not-for-profit PDP dedicated to the discovery, development, and delivery of better, faster-acting, and more affordable TB drugs. TB Alliance and its diverse and extensive network of partners have made significant strides in TB drug development, including the development of a shorter, simpler, more effective, all-oral treatment for highly drug-resistant TB and child-friendly treatments for drug-sensitive TB. They are building a robust portfolio of new TB drug candidates, while advancing the way TB research is conducted.

TB Alliance

partner case study: TB Alliance

In 2019, the U.S. Food and Drug Administration (FDA) approved pretomanid for use as part of TB Alliance's "BPaL regimen" for the treatment of highly drug-resistant forms of TB; a regimen that has revolutionised the management of DR-TB. Since its approval, pretomanid's availability and accessibility have expanded globally. The WHO now endorses the BPaL regimen as the standard treatment for nearly all forms of DR-TB. Notably, pretomanid is only the second drug for DR-TB to be approved by the FDA in over 40 years and the first to be approved as part of a complete treatment regimen. It is also the first such drug developed and registered by a non-profit organisation. The BPaL regimen, a three-drug, all-oral treatment lasting six months, has demonstrated remarkable efficacy in clinical trials, curing 90% of patients with highly resistant TB. BPaL generally reduces the cost per successful treatment by 65–80%, and the full adoption of new therapies could save governments around the world up to $740 million per year.

Throughout the development of pretomanid, TB Alliance has collaborated with and received significant support from numerous governments, academia, philanthropic institutions, the private sector, civil society organisations, and other partners. This network of partners is representative of the unique capabilities of PDPs to build diverse and effective coalitions to drive global health innovation. Since its U.S. approval, TB Alliance has continued to work with pharmaceutical companies for global commercialisation and has included pretomanid in the Stop TB Partnership's Global Drug Facility, expanding its availability to over 130 countries.[31]

TB Alliance pioneered the regimen development model for TB, focusing on creating a complete treatment regimen rather than adding a single drug to existing therapies. This approach can markedly accelerate clinical development, protect new drugs from developing resistance, and ensure that there is rigorous clinical evidence for the use of a specific combination. The model has set a new standard in TB research and can be applied to other multi-agent treatments. TB Alliance has demonstrated for the first time that a PDP can execute end-to-end product development and bring a novel compound from early research to stringent regulatory approval, market introduction, and commercialisation. Within just four years of FDA approval, pretomanid in the BPaL/M regimen has received 28 regulatory approvals, with 42,000 patient courses shipped to 78 countries. Its prequalification by WHO in 2021 and inclusion in the Essential Medicines List in 2023 have significantly improved access to this life-saving treatment, particularly in low- and middle-income countries.

Joi's story

Image 9. *Source: Joegene Mangilaya.*

Joegene 'Joi' is a multidrug-resistant-TB (MDR-TB) survivor and advocate from the Philippines. Joi was initially diagnosed with drug-susceptible TB via a close contact screening and started on treatment. Soon after Joi started the treatment he experienced severe side effects from the drugs, became very unwell, and was hospitalised. Over a period of three months, additional tests showed Joi had been misdiagnosed and actually had MDR-TB, meaning that Joi was resistant to more than one of the first line TB drugs and required stronger drugs to treat the TB disease.

DR-TB treatment has a high pill burden requiring people to take the drugs daily and have their health monitored. For Joi, who was already unwell from treatment, the three hour travel to get his medication was a big undertaking. Having TB significantly impacted Joi's life. He had to leave his job in the technology sector due to ill health. He also suffered poor mental health due to the intense treatment regimen and, at one point, stopped taking medication due to the severe side effects.

In July 2022, Joi became one of the first people to be treated by the shorter all-oral drug treatment for DR-TB, known as BPaL. The new treatment had fewer side effects, and Joi could finally start to feel better. Under Doctor Nassi at the TB Pavilion, Joi was part of the research programme administering the new shorter drug treatment. The treatment had a lower pill burden and could be completed in as little as six months, compared to 18 months on the old treatment regimen.

By December 2022, Joi had completed his treatment and was able to regain his strength physically and mentally. Joi is now a strong advocate in the Philippines, working with TBPeople Philippines and TB Alliance through the **Fast Track the Cure** initiative.[32] Joi shares his story to support others with TB, helping them manage their treatment and inspire hope.

securing access

While new technologies are being developed to better diagnose and treat TB, it's crucial to ensure that these tools reach the populations who need them. This is where **Unitaid's** unique position as a pathfinder for innovation comes in. Unitaid saves lives by making cutting-edge health products available and affordable for people in low- and middle-income countries as quickly as possible. Unitaid identifies innovative treatments, tests, and tools, helps tackle the market barriers that are holding them back, and gets them to the people who need them most. As the leading multilateral funder of TB R&D, Unitaid is committed to making new TB innovations for prevention, detection, and treatment widely available to support people-centred quality care.

Unitaid

partner case study: Unitaid

Unitaid is working with partners to make available new technologies for at-risk populations that are traditionally underserved, including children, pregnant women, and people living with HIV. Diagnosing and treating TB in children, for instance, presents unique challenges and has been largely neglected. Each year, about a quarter of a million children die from TB, almost all without treatment.[25] The lack of appropriately dosed, child-friendly medicines has led to reliance on varying and imprecise treatment practices such as splitting pills, which can lead to continued illness or death, and drug-resistance.

In response to this challenge, Unitaid funded the STEP-TB project, implemented by TB Alliance and the WHO, launching the first TB medicines for children – fruit-flavoured, water dispersible tablets with clear dosing for children of different weights and ages. This was a long overdue advance in care. This success then led to further work by Unitaid and its partners on better formulations to treat DR-TB in children and prevent illness in at-risk populations from all forms of TB.[33]

During and after the project, partners developed policies to facilitate the use of the new medicines, provided technical assistance, and allocated funds to introduce the medicines and widen their availability. The Stop TB Partnership's **Global Drug Facility** has been the main procurement channel for the new child-friendly regimen. The project worked with the WHO and the **Global Fund to Fight AIDS, Tuberculosis and Malaria** to remove obstacles to introducing the drugs. The WHO issued a policy statement urging the rapid introduction of these medicines, and the Global Fund provided guidance on phasing out outdated products. These coordinated efforts eased the transition to the new medicines.

Appropriately dosed child-friendly TB medicines significantly improve treatment outcomes and help fight drug-resistance. Unitaid's strategic investments, combined with the work of Global Drug Facility and other partners, are pivotal in the fight against childhood TB. It is vital to support these efforts to ensure the million children affected by TB each year are swiftly and accurately identified and diagnosed, followed by successful treatment with the most appropriate and child-friendly medicines.

Image 10. *Source: TB Alliance.*

Caption: Children holding the first appropriately dosed, child-friendly paediatric TB medicines. Unitaid funded the new formulation following new WHO guidelines that made older formulations obsolete.

increasing protection

The quest to end TB is severely hampered by our reliance on a single vaccine, the Bacille Calmette-Guérin (BCG), which was introduced in 1921 and has serious limitations. While BCG is one of the most widely administered vaccines in human history, its effectiveness is limited, particularly among adolescents and adults. It provides reliable protection only against severe forms of TB in very young children, and its effectiveness wanes dramatically after adolescence. It is also ineffective in protecting against DR-TB, which is an increasingly serious threat. This century-old vaccine underscores the urgent need for better solutions to protect the billions exposed to TB bacteria.

We urgently need a vaccine that is more effective in protecting all age groups, from all forms of TB. Researchers around the world are closer than ever to introducing a new, more effective vaccine against TB. There are currently 15 candidates in the development pipeline.[34] After over 100 years with a single vaccine, such innovation is injecting a renewed sense of optimism into the TB movement. A TB vaccine that is 75% effective could prevent up to 12 million TB deaths and 42 million treatments for AMR, saving $3.2 billion in treatment costs between 2025 and 2050.[35]

Partners like **IAVI** are leading the quest to bring new TB vaccines to life. IAVI is a non-profit that develops vaccines and antibodies for HIV, TB, and emerging infectious diseases by collaborating with partners around the world to develop safe, effective, and accessible vaccines. They collaborate globally to advance the most promising TB vaccine candidates from discovery through clinical trials to post-licensure access. IAVI also leads policy and advocacy initiatives, engaging with international partners to support TB vaccine development and ensure equitable access. Their approach is both disease-specific and cross-cutting, driven by needs and rights, to effectively mobilise comprehensive responses to disease prevention.

partner case study: IAVI

IAVI is partnering with the Spanish biopharmaceutical company Biofabri in the advanced clinical development of the MTBVAC vaccine candidate to see if it prevents TB disease in infants, adolescents, and adults. MTBVAC is the only live, attenuated vaccine candidate derived from mycobacterium tuberculosis and uses a weakened, harmless form of the pathogen to stimulate an immune response.

IAVI is currently preparing for a Phase 2b clinical trial that is anticipated to start in late 2024. This late-stage efficacy trial aims to enrol 4,300 adult and adolescent participants across 15 sites in South Africa, Kenya, and Tanzania. If the vaccine candidate, called MTBVAC, is shown to safely prevent TB disease, it could be critically important in global efforts to suppress the TB pandemic given its ease of use, single dose, low-cost manufacturing process, and anticipated widespread availability. IAVI and its partners are committed to the affordability of MTBVAC and ensuring that there is sufficient global supply capacity, supply security, and regional equity, with manufacturing partners lined up in Europe, India, and South America.

IAVI also spearheads policy and advocacy initiatives, including as co-lead of the TB Vaccine Advocacy Roadmap (TB Vax ARM), a global coalition of TB stakeholders that seeks to provide coordinated advocacy efforts in support of the TB vaccine agenda, and as host of the Stop TB Partnership Working Group on New TB Vaccines.

Image 11. *Source: IAVI.*

The **WHO TB Vaccine Accelerator Council**, launched in 2023, aims to speed up the development, testing, and equitable deployment of new TB vaccines. The Council includes representatives from high-burden countries, major funder countries, and international financing and procurement agencies. Its priorities include identifying innovative sustainable financial solutions and partnerships, market incentives to rapidly and equitably manufacture and distribute vaccines at scale, and advocacy with relevant decision-makers to strengthen commitment and concerted action, including through political platforms such as the African Union, ASEAN, BRICS, G20, G7 and others. Advocates are demanding that the Council facilitates increased and joint investments of late-stage candidates through licensure as an immediate priority.[36]

While numerous partners across private, public, philanthropic, and academic networks are working to bring the first TB vaccine in over a century to life, more can be done. Siloed approaches to global health innovation limit the impact that existing researchers and manufacturers could have across disease areas. Integrating TB vaccine development into broader global health initiatives is essential.

For instance, partners who are already working on the development of vaccines should be expanding their mandates to include work on TB. The **Coalition for Epidemic Preparedness Innovations (CEPI)**, for example, has a tremendous opportunity to influence the research and manufacturing capabilities necessary to bring about a new TB vaccine. CEPI was launched in 2017 as an innovative partnership between public, private, philanthropic, and civil society organisations. Its mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need. CEPI has supported the development of more than 50 vaccine candidates or platform technologies against multiple known high-risk pathogens or a future Disease X. Central to CEPI's pandemic-beating five-year plan for 2022-2026 is the '100 Days Mission' to compress the time taken to develop safe, effective, globally accessible vaccines against new threats to just 100 days.[37]

While CEPI's current priority pathogens do not include TB, as they focus primarily on viral infections, there is a strong rationale for why CEPI should expand its mandate to include work on TB. For example, CEPI's support for clinical trials and laboratory infrastructure, primarily aimed at accelerating R&D for CEPI priority pathogens and future Disease X outbreaks, could also enhance global R&D capacity for bacterial pathogens like TB. Additionally, CEPI's manufacturing investments could complement and enable other vaccine research efforts. By working with partners on their investment pipeline, CEPI is exploring opportunities to co-invest in TB research, leveraging the benefits of syndicating investments and infrastructure. CEPI should take these recommendations forward to contribute to and bolster the TB response.

ensuring equitable access through collaboration

The path to overcoming TB requires not only substantial investments in R&D to create better tools but also a concerted effort to ensure these tools are accessible to those who need them most. New vaccines, diagnostic tests, and treatments are only effective if they are accessible. Equitable access will not occur on its own; it requires deliberately designing it into the innovation process so that access is not an afterthought.[38] The communities in need of these tools, including women and children, must be involved throughout the development and dissemination strategy. Not only will this ensure that tools are created with the end user in mind, but the involvement of community members can mitigate hesitancy and mistrust, increasing the uptake and impact of new technologies. A comprehensive approach is therefore required - one that not only fosters the development of these tools but also ensures their widespread and equitable distribution.

Global health stakeholders must work collaboratively to address this dual challenge. We must not only innovate but also create robust systems for implementation and delivery. An equity-focused approach to distribution is essential, ensuring that everyone benefits from scientific advancements. PDPs are particularly well-suited to this task, as they engage directly with affected communities through targeted research and consultative processes, ensuring that the needs of those most impacted by TB are at the forefront of innovation. In this way, new tools are developed with the end user in mind, limiting potential barriers that could arise in low-resource settings.

To complement the role of PDPs and other product developers, global health institutions like the Global Fund play a crucial role in the distribution of new tools. The Global Fund should continue to work closely with partners like Gavi, the Vaccine Alliance, Unitaid, and PDPs like FIND, TB Alliance, and IAVI, to bridge the gap between innovation and implementation. With the prospects of a new TB vaccine in the coming years, now is the time for all stakeholders to prepare for an effective and equitable distribution plan. Recognising the complementary and unique value adds of each player in the TB R&D ecosystem, funders must provide investments across the entire TB continuum of care. By supporting the work of product developers and implementers, donors can meaningfully and sustainably contribute to TB elimination.

the time for action is now

Overcoming TB will require more than just scientific breakthroughs; it demands a holistic approach that seamlessly integrates product development with equitable access to healthcare. To maximise the impact of TB innovations, considerations of affordability, availability, and accessibility must be embedded throughout the R&D process. Achieving global TB elimination targets will require increased and sustained financial commitments, as well as bold structural and legal reforms. Donor governments must take the lead, providing the necessary funding and political support to bring new TB innovations to life and ensure these life-saving tools reach those most in need.

The benefits of improving access to health technologies extend far beyond healthcare alone, enabling people to lead healthier, more productive lives and driving economic growth. But at its core, this is about people. It's about safeguarding the billions of people exposed to TB bacteria, ensuring timely and accurate diagnoses, and improving treatment outcomes. It's about fulfilling our global commitment to health equity and advancing progress toward the Sustainable Development Goals. This is about ending the world's deadliest infectious disease once and for all. The time for ambitious, unified action is now - action that can eradicate TB and secure a healthier, more just future for all.

Image 12.
Source: Results Canada

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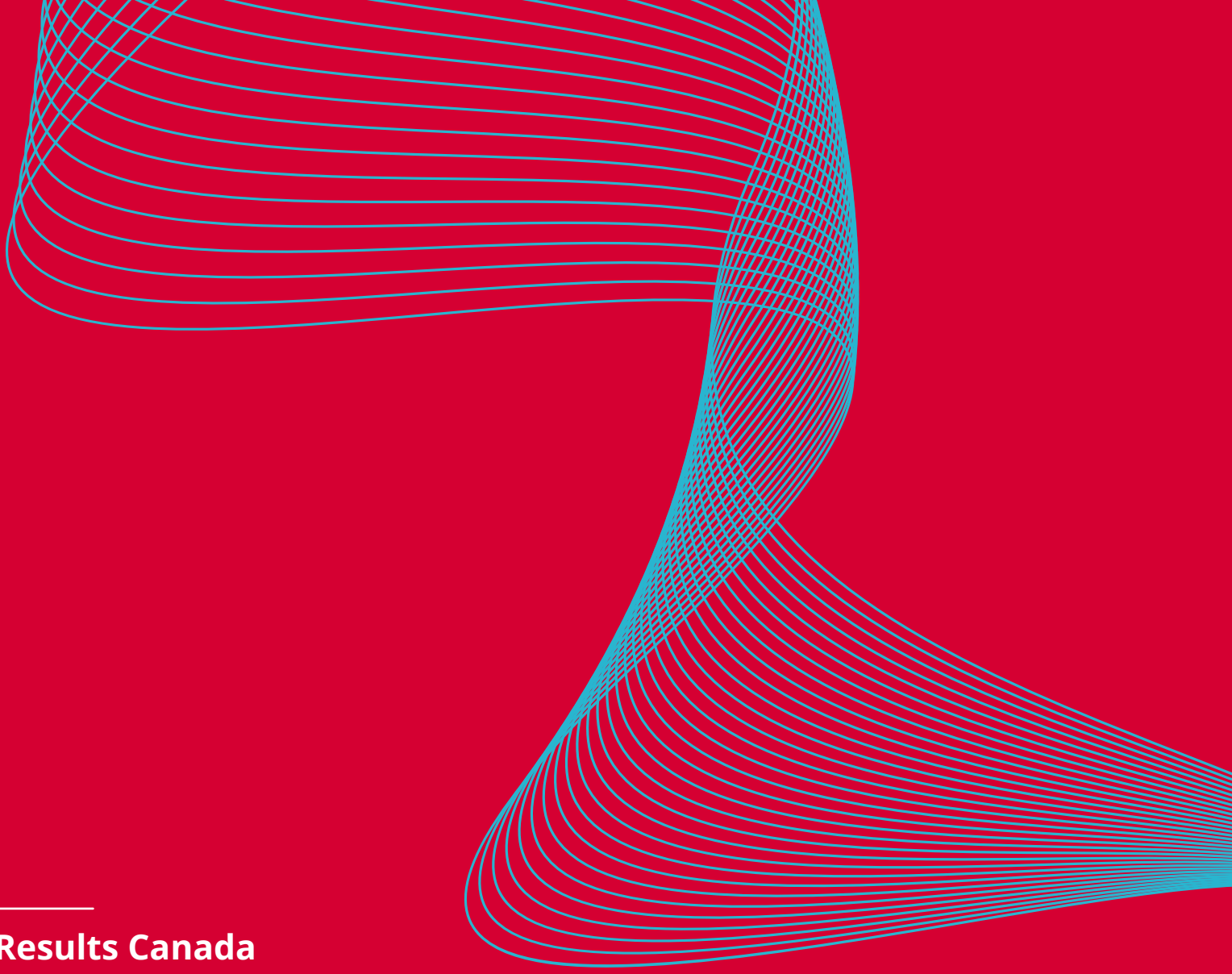

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