

# The urgent need for new TB vaccines

It's time our leaders fulfilled their promises to deliver **new TB vaccines** to end TB. We won't end the epidemic without them.

## THE DEVASTATING IMPACT OF TB

Tuberculosis (TB), declared a public health emergency by the World Health Organization (WHO) in 1993, remains a major global health threat, **killing more than 4,000 people every day**. Tragically, it has recently been confirmed that in 2020 in the wake of COVID-19 the number of people dying from TB increased for the first time in over a decade to 1.5 million people. Even in the face of COVID-19, which killed 1.7 million people in 2020, TB remained the leading infectious cause of death in much of the world. Further, TB is one of the major contributors to the global public health and security threat of antimicrobial resistance (AMR). At present, we are far off course to meeting the global targets to end TB by 2030 endorsed at the United Nations High-Level Meeting to End TB in 2018, as set forth in the UN Sustainable Development Goal 3 on health. **This cannot be achieved without new vaccines, diagnostics, and drugs.**

## PRIORITISING PEOPLE AFFECTED BY TB

TB is a disease of injustice. Of the people who fall sick with TB, **over 90% of them live in developing and emerging economies**, wreaking enormous socio-economic burdens on them and their families and communities. TB is also the leading cause of death among people living with HIV, with 214,000 people living with HIV dying of TB in 2020. The recent report '[A Deadly Divide: TB Commitments vs TB Realities](#)' by the Stop TB Partnership's Community Delegations, notes that vaccines are a key priority of TB-affected communities and calls for leveraging investments in COVID-19 to help end TB. **People affected by TB must be prioritised and play a central role in the global TB response.**

## THE BCG VACCINE IS NOT ENOUGH

We have seen unprecedented collaboration in the development of COVID-19 vaccines since the pandemic began, yet there is only one available TB vaccine — the century old Bacille Calmette Guérin (BCG). While BCG offers important but incomplete protection against the most severe forms of TB, such as TB meningitis, in infants and young children, it is mostly ineffective in adolescents and adults, who are most at risk of developing and spreading TB. No infectious disease has ever been eradicated without an effective vaccine — TB is no exception. **New, more effective vaccines that protect against all forms of TB in all age groups and populations are urgently needed and will be essential to end TB by 2030.**

## WE NEED NEW TOOLS TO END TB

TB diagnostics and therapeutics fall far short of what people with TB need. Each year, millions of people with active TB infections go undiagnosed and remain at risk of spreading the disease. With only a handful of new TB drugs developed in the past 50 years, those who receive a diagnosis face complex treatment regimens that take months or years, with many debilitating and deadly side effects, including deafness and nerve damage. Understandably, adherence to treatment can be poor, contributing to TB as a key driver of AMR. **Innovation needs to be fueled across the board to effectively ensure the end of TB.**

To end TB by 2030, we need world leaders to provide at least

**US\$1 billion per year**

towards TB vaccine research and development.



## TB BY THE NUMBERS



**10 MILLION**

people developed TB disease in 2020, including 1.1 million children



**1.5 MILLION**

people died of TB disease in 2020, including 240,000 children



**1 IN 4 PEOPLE**

may be infected with TB globally



**US\$1.1 BILLION**

annual funding gap for TB research



**800,000**

new TB cases among people living with HIV in 2020



**ALMOST 160,000**

new drug-resistant TB diagnoses in 2020

## THE PROMISE OF NEW TB VACCINES

A vaccine with an efficacy as low as 40% and protective for five years could still reduce approximately 24% of TB cases in low- and middle-income countries if targeted at adolescents and adults. A vaccine with an efficacy of 80% and with lifelong protection could prevent some 70% of TB cases in these countries. Prevention of TB among these populations would dramatically reduce transmission. **Vaccines targeted only at infants are projected to be far less effective at decreasing the TB disease burden** and would not be cost-effective before 2050. Vaccines for adolescents and adults would be cost-effective and potentially cost-saving, assuming a duration of protection of 10 years or longer or an efficacy greater than or equal to 20%.

## TACKLING DRUG-RESISTANT TB

Multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB are both on the rise. Of the half a million people estimated to fall sick with drug-resistant TB each year, only 157,000 were diagnosed in 2020. For people with MDR-TB, treatment can include an astonishing 14,000 pills over two years and eight months of daily injections. Moreover, treating drug-resistant TB is estimated to be between 9-25 times more expensive than treating drug-susceptible TB. Globally, MDR-TB is estimated to account for one-third of all AMR-related deaths and drug-resistant TB deaths could cost the global economy US\$16.7 trillion by 2030.

### New TB vaccines would address AMR in several ways:

- Likely to be equally effective against drug-resistant and drug-sensitive TB
- Reduce the need for antibiotics by preventing TB disease
- Therapeutic vaccines, used in combination with drugs, could reduce treatment duration and reduce the risk of recurrence

## SETBACKS FROM COVID-19

COVID-19 may have set back the fight against TB by up to 12 years, with conservative estimates suggesting an additional 6.3 million people will fall ill with TB and an additional 1.4 million people will die of TB over the next five years, including 400,000 in 2020 alone. Without immediate action to mitigate these setbacks we will stray farther off course to reach the global targets to end TB by 2030. TB research has also been impacted by the pandemic, stretching already limited resources — from trial enrolment and support and monitoring of research participants to reduced and reallocated lab capacity — threatening the progress of critical work and timely delivery of results.

## NEW TB VACCINES ARE ON THE HORIZON

Recent significant trial results suggest new effective TB vaccines can be developed this decade if appropriate investments are made. Across the pipeline, there are six novel TB vaccine candidates in late-stage trials and other promising candidates are in clinical and preclinical stages. Moreover, there are ongoing efforts across the TB research community to broaden the diversity of immune responses through innovative and emerging platforms, such as nucleic acid vector approaches, antibody mediated protection, and improved protein adjuvant combinations. As the pipeline progresses, so do the resources needed, with the late development stage requiring up to 70% of the R&D budget. **Funders must invest in all phases of research, lead efforts for a concerted multi-stakeholder partnership for TB vaccine R&D, and develop a plan for access and community engagement** to bring the first of a new generation of safe and effective TB vaccines to the people who need them most.

## ENSURING A FULLY FUNDED AND RESOURCED TB VACCINE PIPELINE BY 2023

**We need a fully funded and resourced TB vaccine pipeline by 2023 to deliver new TB vaccines and achieve the 2030 End TB goals.** Notwithstanding the challenges of TB vaccine science, the main barrier to achieving this is lack of funding. In 2019, TB vaccine R&D received only \$117 million. In comparison, public investment in R&D for COVID-19 vaccines reached over \$100 billion by January 2021. A modest yet meaningful fraction of this investment would prove transformational for delivering new TB vaccines, with the potential to prevent needless sickness and death for millions of people.

## INVEST IN TB R&D TO INVEST IN PANDEMIC PREPAREDNESS

**The world needs flexible, adaptable, and sustainable global health R&D funding, capacity, and infrastructure to successfully address future pandemics.** In June 2021, world leaders from the G7 announced an ambitious strategy to develop safe, effective vaccines ready to be produced at scale for equitable global deployment in under 100 days in the event of future pandemic threats. Yet, 100 years on, BCG remains the only available TB vaccine. While a 100-day target may be unrealistic for a TB vaccine, **the magnitude of this disease necessitates vastly accelerated vaccine development.** Investing in TB R&D can build local and global research capacities across the breadth of the research continuum, addressing the burden of TB and ensuring the world has the infrastructure in place to address future threats.

## TB VAX ARM

The TB Vaccine Advocacy Roadmap (TB Vax ARM) represents a global coalition of TB stakeholders, including TB survivors, civil society organizations, and non-profits, invested in TB vaccine advocacy and research.

## TB VACCINE DEVELOPMENT IS AT A CRITICAL JUNCTURE

After decades of hard fought scientific progress, we are just now making breakthroughs in clinical efficacy trials, animal models, and new candidates that will inform the next generation of research and clinical development. If these advances are slowed, the world is likely to lose 10-20 years of progress towards a successful vaccine. **We now need to accelerate the development of TB vaccines:** we need to confirm the results of recent studies, test TB vaccines in broader populations, plan for licensure trials, and develop roadmaps to ensure prompt and equitable access to future TB vaccines.

### TB VACCINE PIPELINE SNAPSHOT



#### 15+ TRIALS IN OVERALL PIPELINE

Including whole-cell, subunit, and viral-vector candidates in all phases



#### 6 LATE-STAGE TRIALS

Including whole-cell and subunit in Phase II proof-of-concept to Phase III

## IT'S TIME TO FULFIL COMMITMENTS TO TB R&D

TB R&D has been chronically underfunded in relation to the impact of TB upon global health. At the United Nations High-Level Meeting to End TB in 2018, world leaders pledged to deliver at least \$2 billion annually for TB research, of which \$550 million was earmarked for vaccines. Despite these commitments, TB research is impeded by an annual \$1.1 billion shortfall, while funding for TB vaccines has never exceeded \$120M million per year, further increasing the annual need. We need to make up for lost time. **We call on world leaders to uphold global commitments to end TB by 2030 by ensuring an annual investment of at least \$1 billion to deliver a fully funded and resourced TB vaccine pipeline by 2023 so that new TB vaccines are possible as early as 2025.**

### 4 reasons why we need new TB vaccines to End TB

1

The BCG vaccine is the only available vaccine and offers little to no protection in adults

2

New vaccines could eliminate adherence and stigma problems associated with TB treatment

3

New vaccines would reduce the incidence of drug-resistant TB, a key driver of AMR

4

New vaccines would prevent TB transmission, having a significant impact on the epidemic

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