

The urgent need for a TB vaccine



Translating science
into global health impact

A vaccine is necessary to end the TB pandemic. IAVI and partners continue to make strides to reach this goal.

A global public health emergency

Tuberculosis (TB), declared a public health emergency by the World Health Organization (WHO) in 1993, remains a major global health threat. Before COVID-19, TB killed more people than any other single infectious disease. As the COVID-19 pandemic has waned, TB once again kills more people — approximately 1.5 million per year, more than 3,424 people every day — than any other infectious disease in much of the world. Additionally, TB is one of the main drivers of the growing global antimicrobial resistance crisis, with multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) both on the rise. These forms of drug-resistant TB are very difficult and expensive to treat and carry an increased risk of treatment failure and death than for drug-sensitive TB.

TB is primarily a disease of poverty. More than 80% of people who fall ill with TB live in developing and emerging economies, imposing an enormous socio-economic burden on patients, families, and communities. In 2014, the WHO adopted an End TB Strategy, calling for a reduction in TB deaths of 90% by 2030, as compared to 2015. ([WHO End TB Strategy, 2014](#)) Tragically, we are nowhere near achieving these goals, as the net reduction in TB deaths between 2015 and 2023 reached only 23%. These goals will only be achievable through the introduction of vaccines capable of preventing the development of TB disease in adolescents and adults, among whom most disease and transmission occurs.

Limited impact of existing vaccine

The only available TB vaccine is the more than 100-year-old bacillus Calmette-Guérin (BCG). BCG is effective in protecting infants and young children against developing severe TB disease, such as TB meningitis and miliary TB. Among adolescents without evidence of prior M.tb infection, BCG generally offers variable and mostly poor protection against TB disease in the lungs in adolescents and adults. New vaccines capable of preventing TB disease in adolescents and adults are essential in stopping the ongoing TB epidemic.

TB by the numbers



10.8 million
people developed TB disease
in 2023



1.25 million
people died of TB disease
in 2023



25% of people
globally may be infected
with TB



\$1.25 billion
annual funding need for
TB vaccine R&D



8.2 million new TB cases
diagnosed in 2023

TB R&D shortfall

TB R&D has been chronically underfunded in relation to the impact of TB upon global health. At the United Nations High-Level Meeting on TB in 2023, world leaders pledged to deliver US\$5 billion per year for TB research by 2027. The Global Plan to End TB 2023-2030 projects that an annual investment of \$1.25 billion will be needed for TB vaccine R&D if we are to have a chance of reaching the End TB targets: decreasing TB mortality by 90% and decreasing new cases of TB by 80% in 2030 as compared to 2015 rates. Despite these commitments, annual

investments in TB research only exceeded \$1 billion for the first time in 2021, while funding for TB vaccines only exceeded \$200 million per year for the first time in 2023 ([Treatment Action Group, TB Research Funding Trends Report 2025](#)), greatly hindering the development of new, desperately needed TB vaccines.

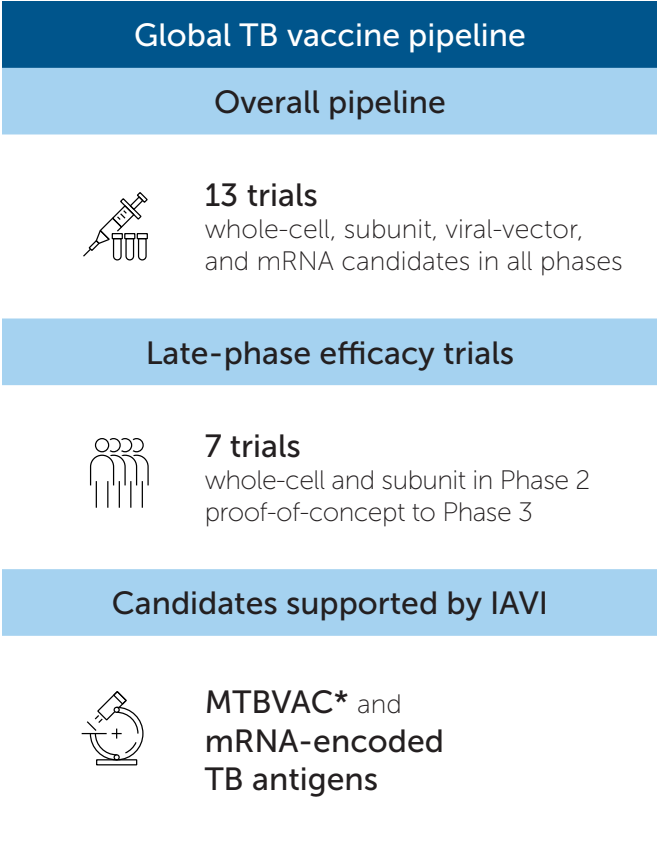
TB vaccine development is at a critical juncture

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. Multiple novel TB vaccine candidates are now in late-stage efficacy trials; their ongoing study will only be possible if sufficient funding is made available to conduct these complex, expensive trials. If these advances are slowed, the world is likely to lose up to 10 years of progress toward a successful vaccine. We need to accelerate the development of TB vaccines by removing financial obstacles to conducting Phase 3 licensure studies; supporting research and development of new, even more promising TB vaccine strategies; testing TB vaccines in broader populations; and developing strategies to ensure prompt and equitable access to future TB vaccines.

New TB vaccines on the horizon

Recent results from clinical trials provide hope that new, effective TB vaccines can be licensed and utilized globally in the coming decade if appropriate investments are made in clinical trials to assess vaccine safety and efficacy, and to ensure that these vaccines, once licensed, will be accessible to those most at risk of developing and spreading TB. Moreover, there are ongoing efforts to broaden the diversity of immune responses through innovative

and emerging platforms, such as mRNA approaches, and improved protein-adjuvant combinations. Funders must invest in all phases of research and develop a plan for access to bring the first of a new generation of safe and effective TB vaccines to the people who need them most. As the pipeline progresses, so do the resources needed, with the late development stage requiring up to 70% of the estimated R&D budget.



* Trials in adults and adolescents. Biofabri is leading clinical development of the candidate in infants (currently in a Phase 3 trial).

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