

Member States must commit to invest in TB vaccine R&D

Member States have a historic opportunity to finally end TB by committing to develop and roll-out new TB vaccines within the next five years at the United Nations High-Level Meeting (HLM) on TB.

IT'S TIME TO MOBILIZE JOINT FINANCIAL SUPPORT AND ENSURE UNIVERSAL ACCESS TO NEW TB VACCINES

Member States need to bring together different governments and interested parties for coordinated investments to meet the US\$1.25 billion annual funding target to advance TB vaccine development. The COVID-19 response, underpinned by unparalleled multilateral and multi-stakeholder collaboration, offers key lessons to meet the resourcing needs of the field. This response must include the diversification of funding streams, innovative and custom funding mechanisms, and the incentivization of industry partners, such as through de-risking investments.

Member States must likewise commit to equitably available, accessible, acceptable, and affordable new TB vaccines, acknowledging that most funding for TB research comes from the public sector. As such, Member States should promote the transfer of technology and know-how, and encourage voluntary licensing and local manufacturing in agreements where TB R&D is publicly funded. **Further, Member States must commit to internationally coordinated research and clinical trials, and transparent and rapid data sharing and reporting of research findings and trial results.**

We urgently need new TB vaccines to end TB

TB is the leading cause of death from an infectious disease in much of the world. Amid already constrained financial support for essential TB services and rising levels of drug-resistance, the number of people dying from TB increased for the second year in a row, **killing 1.6 million people in 2021** (up 4.5% from 2020).ⁱ The century old Bacille Calmette Guérin (BCG) is the only one available TB vaccine. While BCG offers important but incomplete protection against the most severe forms of TB in infants and young children, it is mostly ineffective in adolescents and adults, who are most at risk of developing and spreading TB.

We need multiple new TB vaccines that work across all age groups, particularly among adults and adolescents, to meet the WHO 2030 End TB goals.ⁱⁱ Universally accessible TB vaccines would fight antimicrobial resistance (AMR), advance health equity, avert millions in household catastrophic costs, improve affected countries' macroeconomic prospects, and advance pandemic preparedness and response (PPR) infrastructure.

New TB vaccines are possible in the next five years

The urgency of the need is matched by the promise of the science. The pipeline of candidates has never been stronger, with at least five vaccines in phase III efficacy trials and work underway to develop next-generation vaccines based on mRNA and other promising platforms.ⁱⁱⁱ **New TB vaccines could be available this decade – with some ready for licensure within the next five years, by 2028 – but only if Member States substantially increase adequate, predictable, and sustainable financing for TB vaccine R&D.**

Invest in TB vaccines to invest in pandemic preparedness

Preventing future pandemics requires tackling the most serious pandemic threats today. TB stands alongside HIV/AIDS, malaria, viral hepatitis, and AMR as deserving concerted attention within any new PPR initiative or international instrument. **Moreover, the world needs flexible, adaptable, and sustainable global health R&D funding, capacity, and infrastructure for a successful pandemic response.** Investing in TB R&D can build local and global research capacities across the research continuum, driving efficiency in every stage of product development, while addressing the burden of TB and ensuring the world has the infrastructure to address future threats.^{viii}

The time to invest in new TB vaccines is now

At the 2018 TB HLM, Member States pledged to invest US\$2 billion annually in TB R&D over five years. By 2021, only 30% of the target had been invested – for vaccines, this was only 15% against an annual target of \$613 million.^{iv} **Member States must commit to substantially increase financing for TB R&D to \$5 billion per year from 2023**, as outlined in the Global Plan to End TB 2023-2030, and recognize that all Member States must contribute their fair share.^v **This target includes \$1.25 billion per year to develop new safe, effective, and affordable TB vaccines within the next five years.**

The cost of inaction wildly surpasses the cost of action

Every \$1 invested in the development and rollout of new TB vaccines for adolescents and adults will return \$7 to the global economy over 25 years.^{vi} Without immediate action, an estimated 31.8 million TB deaths will occur between 2020 and 2050, resulting in global economic losses of \$17.5 trillion. **We can save up to 23.8 million lives and avert \$13.1 trillion in economic losses if governments meet the WHO 2030 End TB goals.**^{vii}

Existing multilateral mechanisms exclude TB vaccine R&D

The Global Fund is the largest international donor to TB activities, but supports implementation of existing tools, not R&D to develop new tools, like vaccines. Similarly, GAVI leads global efforts to scale-up immunization programs in low- and lower-middle-income countries but does not invest in product development. Conversely, mechanisms like CEPI that focus on vaccine R&D do not prioritize TB. CEPI's 2022–2026 strategy, in line with their investments to date, remains directed toward viral pathogens, not yet TB.

New TB vaccines are key to tackle AMR

Drug-resistant TB (DR-TB) is a leading cause of death due to AMR. Multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB are both on the rise. Of the almost half a million people estimated to have fallen sick with DR-TB in 2021, less than 162,000 accessed treatment.^{ix} Moreover, treating DR-TB is many times more expensive than treating drug-susceptible TB. It has been estimated that new TB vaccines could avert over a third of deaths attributable to bacterial AMR.^x Yet, TB has been left out of many AMR initiatives – a missed opportunity to address the heart of the challenge.

References

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TB 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.

Learn more at www.newtbvaccines.org/take-action