TB VACCINE ACCELERATOR COUNCIL

PROGRESS UPDATE November 2024 – February 2025

ABOUT THIS UPDATE

The update charts progress achieved by the tuberculosis (TB) Vaccine Accelerator Council and its Secretariat between November 2024 and February 2025.

Information presented here is drawn from the activities of the Secretariat and the Council members. The Update specifically highlights progress on implementing the following recommendations made by the Council to the Secretariat at its second meeting in May 2024:

- To convene a high-level TB vaccine financing and access meeting in 2025 and present a set of options that help countries gain timely, reliable access to safe, effective, and affordably priced new TB vaccines.
- To establish working groups to accelerate progress towards the Council's mission, with a
 focus on advancing key priorities such as vaccine development, financing, access, health
 system preparedness, and community engagement.
- To conduct in-country workshops focused on sharing information about the TB vaccine pipeline, discussing national product preferences and deployment plans, and exploring future strategies for vaccine access, financing, and distribution.

The Update is structured as follows:

- 1. Status of global funding for TB vaccine R&D
- 2. Update on the establishment of the TB vaccine finance and access working group
- 3. Strategic preparations for the 2025 high-level TB vaccine financing and access meeting
- 4. Progress in conducting in-country workshops
- 5. Ongoing activities and next steps



The Report from the previous cycle (May-October 2024) can be accessed <u>here</u>.

1. Status of global funding for TB vaccine research and development

TB vaccine research is chronically underfunded, slowing progress in vaccine development. As of August 2024, at least 15 TB vaccine candidates were in clinical development: four in Phase I, five in Phase II, and six in Phase III. These candidates aim to prevent TB infection or disease or improve treatment outcomes. Expanding the pipeline requires a renewed and coordinated commitment to funding basic research, preclinical studies, and clinical trials. According to the latest report from the Treatment Action Group¹, global funding for TB vaccine R&D increased by 58% from 2022 to 2023, reaching \$227 million —a promising step forward in the fight against TB.

However, this amount still remains significantly below the \$1.25 billion annual target set in the *Global Plan to End TB* and represents only a small fraction of the \$5 billion annual funding commitment for TB research and innovation pledged by Member States in the political declaration of the 2023 United Nations High-Level Meeting on TB². The recent funding increase was driven primarily by philanthropic contributions, which more than doubled from \$54 million to \$116 million, followed by a more modest rise in public sector funding, which increased by 18% from \$86 million to \$101 million. Private sector investment remains limited, accounting for only 4% of total funding.

2. Establishment of the finance and access working group

In May 2024, Members of the Council requested the WHO Secretariat to establish working groups to accelerate the achievement of goals aligned to its mission. Four working groups will be established in a phased approach: vaccine research, and innovation; product development, policy & manufacturing; finance & access; and country readiness, advocacy, & community partnership.

The finance and access working group was established in February 2025.

In February 2025, the TB Accelerator launched the <u>Finance and Access Working Group</u> with the goal of ensuring timely, equitable, and sustainably financed access to affordably priced new TB vaccines in all countries with demand based on public health needs. The Working Group held its **first meeting on 14 February 2025** and will continue to meet monthly thereafter. It is **co-convened** by South Africa, WHO, and Gavi, each bringing distinct expertise in vaccine financing and access. Members include representatives of governments, health and development partners, financing institutions, academia, and civil society.

¹ Treatment Action Group. Tuberculosis Research Funding Trends 2005–2023. (https://www.treatmentactiongroup.org/resources/tbrd-report/tbrd-report-2024).

² See United Nations General Assembly resolution 78/5

The **specific goals** of the Working Group are to:

- develop an early understanding of anticipated barriers, bottlenecks and challenges to country financing and access for novel TB vaccines;
- accelerate the identification of financing and access solutions and opportunities to incentivize equitable and affordable global access;
- develop a financing and access options framework, outlining mechanisms that enable countries to have timely and sustainable access to novel TB vaccines;
- coordinate efforts across governments, partners, financing institutions, private sector, and civil society to propose strategic partnerships and financing and access mechanisms, with a particular focus on speeding up vaccine availability and access for high TB-burden countries;
- foster the development and implementation of financing and access strategies that enable countries to have timely and sustainable access to safe, effective, and affordably priced TB vaccines.

3. Preparations for the 2025 high-level TB vaccine financing and access event

In May 2024, Members of the Council requested the WHO Secretariat to convene an access and financing meeting in 2025 and present a set of options that help countries gain timely, reliable access to safe, effective, and affordably priced TB vaccines. WHO and the Government of South Africa are partnering to cohost this event as part of the G20 health ministers' meeting in November 2025.

What: This is a high-level meeting to present financing and access options for novel TB vaccines, developed through a multistakeholder process of the Finance and Access Working Group (see update no. 2) which comprises governments, health and development partners, financing institutions, academia, and civil society. The goal is to foster policy dialogue and cross-sectoral collaboration to promote the sustainable supply and equitable access to safe, effective, and affordably priced TB vaccines.

Why: Although high demand for a TB vaccine is anticipated, production capacity challenges could emerge unless demand forecasting and supply chain management are optimized. Additionally, there is a risk of supply bottlenecks, as the production of some vaccine candidates may rely on a single primary supplier. With TB predominantly affecting low- and middle-income countries and having limited market potential in high-income regions, a strategic approach to market shaping is crucial. To address these challenges, global and regional partners, manufacturers, countries, and international agencies must take concerted action to correct market imbalances, foster the development of a robust TB vaccine market, and facilitate timely access.

When: Given that G20 member countries and regions account for at least 70% of the global TB burden, WHO and the Government of South Africa are partnering to co-host this event as part of the G20 health ministers' meeting in November 2025.

4. Country workshops



In May 2024, the Council supported plans to conduct in-country workshops focused on sharing information about the TB vaccine pipeline, discussing national product preferences and plans, and exploring future strategies for vaccine deployment, access, and financing.

In partnership with Indonesia's Ministry of Health, WHO convened the first workshop of this kind 8-9 November 2024 in Bali, Indonesia ahead of the Union World Conference on Lung Health to discuss anticipated use cases, programmatic requirements, potential demand, and strategies for TB vaccine procurement, financing, and access.



A second workshop is scheduled to take place in South Africa in mid-2025.

5. Ongoing activities and next steps

- January 2025: WHO established a Technical Advisory Group (TAG) to provide independent evaluations and optimize efforts related to regulatory, clinical, and policy aspects of TB vaccine candidates in late-stage development. The TAG will offer guidance on data requirements and regulatory strategies, advise on policy formulation and implementation, and assist in developing WHO guidance to accelerate vaccine introduction globally.
- May 2025: The third annual in-person meeting of the TB Vaccine Accelerator Council will be held on the sidelines of the World Health Assembly on 20 May 2025. Invitations to Council members will be sent out in March.

Next steps

The next quarterly update will be made available in the second quarter of 2025.

If you have any questions in the meantime, please feel free to reach out to TBvaccines@who.int.