
TB VACCINE ACCELERATOR COUNCIL

PROGRESS UPDATE *March – December 2025*

ABOUT THIS UPDATE

Now, at the end of its second year, this update reviews activities achieved by the tuberculosis (TB) Vaccine Accelerator and its Secretariat between March and December 2025, under strategic steer from the TB Vaccine Accelerator Council. Substantial progress has been made in three technical and strategic areas, namely Product Development, Manufacturing and Policy (related to Working Group 2 (WG2)); Finance and Access (WG3) and Country Readiness, Advocacy and Community Partnership (WG4).

Information presented here is drawn from the activities of the Secretariat and the Accelerator working groups. The Update specifically highlights progress on implementing the following recommendations made by the Council to the Secretariat at its third meeting in May 2025:

- To prioritize the establishment of Working Group 4 (WG4) on Country Readiness, Advocacy and Community Partnership.
- To leverage the October 2025 G20 Health Ministers Meeting to elevate TB vaccine financing and access on the global health agenda and to encourage increased domestic financing for novel TB vaccines and regionally diversified manufacturing, with the aim to foster long-term sustainability.
- To support evaluation of the potential impact of new TB vaccines within an integrated approach to TB prevention, including within the context of innovation in TB diagnostics and preventative treatment, and countries' immunization national immunization strategies.

As of 2025, the Secretariat and the activities described herein have been funded by the Gates Foundation and Wellcome Trust.

The Update is structured as follows:

- 1. Strategic Advisory Group of Experts on Immunization (SAGE) session on new tuberculosis vaccines (related to WG2)**
- 2. Launch of Finance and Access solutions at G20 Health Ministers Meeting in South Africa (WG3)**
- 3. Update on the establishment of the Working Group 4 on Country Readiness, Advocacy and Community Partnership (WG4)**
- 4. Ongoing activities and next steps**



1. Strategic Advisory Group of Experts (SAGE) session on new tuberculosis vaccines

As a preliminary step to establishing Accelerator Working Group 2 on product development, manufacturing and policy, WHO has established a [Technical Advisory Group \(TAG\) on Evidence for Clinical and Policy Considerations for New Tuberculosis \(TB\) Vaccines](#).

The TAG initiated its work in early 2025, undertaking consultations with developers as part of preparations for a session on new TB vaccines with the WHO Strategic Advisory Group of Experts in Immunization (SAGE) in September 2025. The purpose of the session was to provide an overview of the TB vaccine pipeline, to discuss the data anticipated from ongoing or planned pivotal efficacy trials for the most advanced candidates and to discuss how these may inform a global policy recommendation.

SAGE noted that the results of multi-country, multi-region vaccine clinical trials that will only have adequate statistical power to detect efficacy in one or two high tuberculosis burden countries or single-country clinical trials can be extrapolated to other countries unless there are major epidemiological differences. Immunobridging studies, if a suitable correlate of protection is established, or Phase 4 impact studies may be required to determine effectiveness in other settings or in priority groups where clinical trials were not sufficient for subgroup assessment.

Considering that only a limited number of Interferon Gamma Release Assay (IGRA) negative subjects will be enrolled in the pivotal clinical trials, SAGE advised that provisions should be made to collect adequate data on the safety and immunogenicity of the vaccine in IGRA negative individuals to inform recommendations, since such individuals are likely to be vaccinated during programmatic rollout of the vaccines.

In anticipation of potential trial outcomes (specifically related to differences in IGRA positive vs IGRA negative individuals), SAGE proposed conducting scenario analyses, risk assessment and contingency planning, including the potential efficacy in IGRA negatives, to proactively align and inform decision making. It will be important to ensure commitment from developers and donors to generate these additional data and evidence.

The TAG also initiated a discussion with SAGE on the potential role of asymptomatic TB as a clinical endpoint for future efficacy trials and sought advice on the proposed steps to generate the evidence to assess the clinical relevance of asymptomatic TB. Based on current knowledge, SAGE cautioned that inclusion of asymptomatic tuberculosis as a component of a composite clinical trial endpoint may compromise the demonstration of efficacy against severe tuberculosis, which is considered the most robust strategy for vaccine licensure. Therefore, SAGE supported the assessment of gaps to generate evidence on the characteristics of asymptomatic tuberculosis to enable decision-making with regards to the use of potential composite endpoints in pivotal tuberculosis vaccine trials.

A summary of the full discussion and outcomes of the SAGE meeting are reported in the [SAGE meeting report](#).

In 2026 the TAG will develop TB vaccine evidence scenarios based on possible trial outcomes, identify associated risks for regulatory approval and policy recommendations, and propose risk mitigation strategies. In addition, the TAG aims to publish a gap analysis to identify additional evidence needs to assess the use of asymptomatic TB as part of TB trial endpoints. A consultation with regulators from high TB burden countries on clinical design aspects for TB vaccines intended for adults and adolescents is also planned.

2. Launch of Financing and Access solutions at G20 Health Ministers Meeting in South Africa

The Accelerator [Finance and Access Working Group](#) (F&A WG) was launched in February 2025, tasked with identifying urgently needed solutions to accelerate equitable access and sustainable financing to novel TB vaccines, and to present these solutions at a high-level event by end of 2025. The F&A WG is co-convened by WHO, Gavi and the Government of South Africa and has membership including high-burden member states, civil society representatives, regional development banks, pooled procurement agencies and market shaping and financing institutions.

Between February – October 2025, the Finance and Access Working Group worked at pace to develop a landscape on the current novel TB vaccine finance and access ecosystem, market projections over the next 10 years, anticipated gaps and bottlenecks and needed solutions to

accelerate access for all high-burden countries. This work was summarised in a WHO report '[Catalyzing solutions for equitable global access and sustainable financing for novel tuberculosis vaccines for adults and adolescents.](#)'

The report sets out the F&A Working Group's shared vision for equitable access to novel TB vaccines and advances a shared understanding of the current landscape and its possible evolution in the future. It is a first-of-its-kind analysis of the anticipated barriers, bottlenecks, and market dynamics that could impact timely, equitable, and sustainable access to novel TB vaccines on the horizon. It highlights six urgently needed solutions and priority actions for governments, health partners, funders, suppliers and civil society to accelerate equitable access to novel TB vaccines.

The report was launched at a high-level event co-hosted by the Government of South Africa and WHO at the G20 Health Ministers Meeting in Limpopo, South Africa on 6th November 2025, titled '[Together for a TB-free world: Financing and access solutions for novel tuberculosis vaccines.](#)' The launch event brought together health ministers from around the world, civil society, global health leaders, and financing institutions.

The discussion at the event reinforced political commitment to TB vaccine access and highlighted strong support by G20 governments, international partners, NGOs and civil society on taking forward the solutions identified in the report and stakeholders' commitments to contribute to these efforts. There was broad agreement that the next 12 to 18 months represent a critical window for coordinated global action on access and financing. The meeting concluded with a call for G20 members to translate political momentum into concrete investments, coordinated planning, and strengthened partnerships to guarantee timely and equitable access to future TB vaccines.

The F&A WG will continue to advance this agenda at a global level with a firm commitment to realize the needed solutions. All the members of the F&A WG will continue to actively engage and collaborate with all other key stakeholders (including supply side stakeholders, global funders, civil society and other areas of the TB Vaccine Accelerator). In 2026–2027, the F&A WG will prioritize efforts to design, develop and implement most urgently needed solutions identified in the November 2025 report.

3. Update on the establishment of the Working Group 4 on Country Readiness, Advocacy and Community Partnership

In addition to the [stakeholder workshop on new TB vaccines in Indonesia](#) that was convened in 2024, WHO, in collaboration with the Government of South Africa hosted a country preparedness workshop in Johannesburg, South Africa on the 23rd and 24th of July 2025. The

workshop brought together national decision-makers, technical experts, and civil society representatives to discuss anticipated use cases, delivery strategies, and evidence needs for TB vaccine introduction.

The workshop resulted in a clear pathway for policy decision-making and laid out the potential regulatory pathway. Furthermore, several actionable next steps were outlined related to evidence generation for decision-making, strengthening systems for delivery, community engagement and communication, and coordination and financing. [The report of the event has been published](#). As a next step, South Africa will develop a *Roadmap for Accelerated Implementation of Novel TB Vaccines for Adults and Adolescents in South Africa*. Lessons learned from this workshop will inform future consultations and WG4 activities.

In line with the Council's 2025 recommendation, [WG4 on Country Readiness, Advocacy and Community Partnership](#) was formally established in December 2025 to support countries in preparing for TB vaccine introduction. WG4 focuses on evidence-based decision-making, strengthening delivery systems, and fostering trust through partnerships with civil society and affected communities.

Between September and November, the WHO Secretariat of the TB Vaccine Accelerator convened in-person and virtual events to present and discuss the WG4 concept with regional and country colleagues, civil society, technical partners and funding agencies. Feedback received was incorporated into a concept note describing the objectives and the ways in which WG4 will function. The note identifies the main constituencies to be involved at country level and the themes to focus on during country dialogues.

WG4 will build on the successful consultations in Indonesia and South Africa and conduct a series of country preparedness and thematic workshops to bring together national decision-makers, technical experts, and community representatives to address priority topics such as delivery systems, regulatory alignment, and demand creation. Consultations held to date have assessed country interest and availability to host workshops.

Through the workshops, a Community of Practice will be built in which countries, technical partners and civil society can exchange experiences and co-develop strategies that address common challenges. Over time, this network is expected to strengthen capacity, build trust, and accelerate readiness for equitable TB vaccine introduction.

WG4 will convene its first thematic workshop in early 2026 and aims to hold at least three country, regional or thematic workshops per year.

4. Ongoing activities and next steps

- The Technical Advisory Group on Evidence for Clinical and Policy Considerations for New Tuberculosis (TB) Vaccines is working toward a regulatory consultation in mid-2026.
- The Finance & Access Working Group continues to advance work on financing and access, including operationalizing recommendations from the G20 report.
- Preparations are underway for the launch of the WG4 Community of Practice platform and the first country or thematic workshop in early 2026.
- An Accelerator Summit is planned for 27-28 April 2026 to convene members and partners of the accelerator working groups, and other key stakeholders from the TB and TB vaccine community. The objective of the summit is to present activities and achievements of the Accelerator Working Groups, partners & stakeholders and to identify linkages, synergies and gaps across the three technical and strategic working groups mentioned above. The Summit may be followed by a Funder's Forum.
- The fourth annual in-person meeting of the TB Vaccine Accelerator Council will be held on the sidelines of the World Health Assembly in May 2026. Invitations to Council members will be sent out in March.

The next update will be released in the second quarter of 2026.

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