



**TB Vaccine Access in “4D”:**  
A Roadmap Charting  
Civil Society Actions  
for Equitable Access

## TB Vaccine Access in “4D”

### Introduction

At the 2023 United Nations High-Level Meeting on TB, member states committed to develop and deliver at least one new TB vaccine by 2028.<sup>30</sup> This roadmap seeks to accelerate introduction of, and maximize global access to, new TB vaccines under development by articulating the interventions civil society can make to secure equitable access.

The roadmap eschews a single definition of access in favor of a principles-based approach that acknowledges access to new TB vaccines as a fundamental entitlement rooted in states’ obligations to fulfill the human right to enjoy the benefits and applications of scientific progress (right to science) and the right to enjoy the highest attainable standard of health (right to health). These rights offer a framework for considering access along four lines: availability, accessibility (including affordability), acceptability, and quality – underscored by human rights principles of nondiscrimination, participation, and transparency.

Here, equity is defined as the absence of unfair, avoidable, or remediable differences among and within countries and between groups of people or communities, in line with WHO Pandemic Accord definitions and endorsed by leading ethicists, social scientists, and affected community representatives in the TB response.<sup>31</sup> Equitable access is not the result of a single intervention, but rather the outcome of interlocking actions

by multiple stakeholders. Sometimes these stakeholders will work in concert; occasionally, at odds. This roadmap focuses on the role of an overlooked but indispensable player in immunization policy – civil society – in securing equitable access to new TB vaccines.

### Structure of the Roadmap

The TB vaccine pipeline contains at least 17 vaccine candidates being evaluated at different stages of clinical development and representing different underlying vaccine platforms (Figure 15):<sup>32</sup>

- **Subunit vaccines (protein/adjuvant).**  
Examples: M72/AS01E, GamTBvac
- **Live attenuated vaccines.**  
Examples: MTBVAC, VPM1002
- Inactivated whole-cell vaccines derived from *Mycobacterium tuberculosis* or closely related mycobacteria.  
Examples: Immuvac (MIP), DAR 901

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- **mRNA vaccines.** Examples: BNT164a1 and BNT164b1
- **Viral vector vaccines.** Examples: ChAdOx1.85A+MVA85A, Ad5-105K

This roadmap focuses on the three highlighted vaccine types that are at the center of preparatory activities undertaken by the Finance and Access Working Group of the WHO TB Vaccine Accelerator Council.<sup>33</sup> These vaccines are collectively referred to as “new TB vaccines” in the text.

**T**hese vaccines were chosen to ensure the roadmap considers a variety of access-related factors that are influenced by specific vaccine types, for example clinical trial design, durability of protection, side effects, manufacturing process, storage and transportation, and intellectual property rights. While some candidate vaccines are being studied among infants or tested under other paradigms (prevention of infection, prevention of recurrent TB disease), the discussion here assumes vaccines will be used to prevent TB disease among adolescents and adults, as this is the primary indication for TB vaccine development.

The roadmap outlines a series of recommended actions for CSOs and other stakeholders such as funders, vaccine developers, and manufacturers to take between 2025 and 2030. The earliest normative and regulatory approvals of new TB vaccines are anticipated to occur around 2028, followed

by early introduction and initial implementation leading to policy expansion and broader rollout beginning around 2030.

Recommended actions are organized into four areas: **Development**, **Delivery**, **Demand**, and **Data**. Collectively, these areas offer a “4D” view of interventions to secure equitable access to new TB vaccines.

- **Development** refers to research and clinical trials of the vaccines.
- **Delivery** refers to a set of actions required to provide access to vaccines.
- **Demand** stands for vaccine awareness, preparedness, and uptake among key stakeholders, target groups, and the general population, including people’s intent and willingness to receive the vaccine given its characteristics.
- **Data** refers to collecting information about vaccine implementation to inform follow-up actions and policy expansion, including adverse event reporting, marketing approval status, inclusion in NIPs, and supply disruptions. Data collection cuts across the other three areas.

**F**or each piece of the 4D perspective, the roadmap recommends actions that CSOs and other stakeholder groups should undertake in the ideal scenario. It is not only up to civil society, but also to funders, vaccine developers and manufacturers, multilateral agencies, and

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Figure 15

The TB Vaccine Pipeline (as of April 2025)



governments to turn these ideal scenarios into realities. The recommended actions are intended to inform how stakeholders involved in vaccine research, policy making, and delivery should work with civil society to achieve equitable access to new TB vaccines.

Recommendations are based on an analysis of publicly available information about the TB vaccine pipeline, 22 semistructured interviews with experts representing various sectors and regions, and consultations with national and region-

al civil society organizations, community advisory boards, and communities of people affected by TB. The online Appendix contains a list of stakeholders interviewed and the key documents used to develop the roadmap.

Across the board, interviewees stressed that CSO involvement in vaccine development, as well vaccine delivery, demand creation, and data collection, is essential as communities, being the intended direct beneficiaries of vaccination, should be regarded as co-owners of this whole process.

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The new TB vaccines covered by this roadmap are in different stages of clinical research (see Figure 15).<sup>34</sup> Based on the indicated completion dates of ongoing and future trials, the timeframe for the development stage has been estimated as 2025–2028 for the most advanced candidate, M72/AS01E. For the other two candidates covered by this roadmap – MTBVAC and BNT164 – development will likely extend to 2030 and beyond.

### Action 1

Vaccine developers proactively involve CSOs in the creation of comprehensive research plans to guide clinical trials and other development activities.

The three vaccines covered by the roadmap are positioned differently when it comes to the scope and progress of their clinical trials – from ongoing phase IIa trials (BNT164) to full enrollment in a phase III trial (M72/AS01E). The outcomes of each study will shape further phase II/III trials, as well as post-marketing and phase IV studies if the vaccines show adequate safety and efficacy.

Several key areas in the comprehensive research plan (CRP) require CSO input, including:

- Preferred product characteristics
- Inclusion of key target groups in trials
- Wider geographical coverage of clinical trials
- Innovative trial designs, including head-to-head comparisons of different candidates and studying TB vaccines with TB preventive treatment

The core mechanism by which CSOs can communicate with vaccine developers and other stakeholders is regular community advisory board (CAB) meetings at global,

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regional, national, and site levels. Other communication platforms include scientific and political events related to TB and events in other fields (e.g., HIV meetings). Wider community representation at these events is necessary to support more comprehensive communication between CSOs and vaccine developers.

### Ideal scenario:

Vaccine developers regularly engage with CSOs through CABs and other existing platforms to ensure there are public, and evolving CRPs for vaccine candidates that are open to feedback from the community, as co-owners of the development process.

### CSOs ensure CRPs account for TB vaccine preferred product characteristics as defined by the WHO.

The WHO has defined key TB vaccine product attributes in its *Preferred Product Characteristics for New TB Vaccines* guidance document.<sup>35</sup> Key characteristics include:

- 50% or greater efficacy in preventing confirmed pulmonary TB
- Over 10 years of protection after primary immunization
- Minimal number of doses and boosters
- Favorable safety and reactogenicity profile

- Careful investigations for live platform vaccine candidates

CSOs directly involved in discussions with vaccine developers about the CRP can provide feedback regarding preferred product characteristics based on community needs and perceptions. For instance, interviewees indicated preferences for efficacy in preventing confirmed pulmonary TB over 70% (higher than the 50% minimum efficacy threshold specified by the WHO) and single-shot vaccines. CSOs will play a key role in conversations about product characteristic tradeoffs and acceptable risk/benefit concerning vaccine candidates and their evaluation in particular populations.

### CSOs advocate for inclusion of key populations in CRPs and clinical trials.

The key populations identified include PLHIV, people living with and without *Mycobacterium tuberculosis* infection, and people cured of TB (i.e., TB survivors). Interviewees identified additional groups including pregnant women, people with diabetes, people using drugs, people in penitentiary institutions, military servants, migrants, and medical and outreach personnel working in the field of TB.

Ongoing trials of new TB vaccines have not consistently included these key populations. CSOs should advocate for inclusion of the identified groups in future clinical trials when discussing TB vaccine development plans with developers. Existing



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community-led campaigns can serve as a basis for this work, such as the community consensus on the earlier inclusion of pregnant women and persons in TB research or the advocacy to include people using drugs in trials in the field of HIV.<sup>36,37</sup> CABs should reach out to CSOs representing the respective groups to raise their awareness about TB vaccine trials and collect feedback on specific community needs. Representatives of specific groups can be invited to CAB meetings and involved in developing position papers addressing the inclusion of these groups in clinical trials.

### **Vaccine developers and funders commit to wider geographical coverage of clinical trials and development activities within the CRP.**

Current phase II–III trials are primarily taking place in the African region and in the Southeast Asia region. So far, there are no active trials in Latin America, Eastern Europe and Central Asia, or Middle East and North Africa, even in countries with a high burden of TB.

As shown in the country policy portraits, some countries prefer or require clinical data from their country or from a country in the same region or with similar health

systems, epidemiological conditions, or population characteristics. Vaccine developers should discuss the possibility of including additional countries in future trials with regional CABs and networks of people affected by TB, with CSOs positioned to mediate between vaccine developers and national research institutions.

Interviewees noted that it is important for vaccine developers to have information about the local epidemiology, including hot-spot communities, the local clinical trial infrastructure, and the licensure and procurement requirements before designing phase II–III trials. It can be challenging to involve additional countries after planning begins due to budget or logistics considerations.

Vaccine developers stressed the need for clinical trial site capacitation and building community awareness in countries that have less experience in conducting clinical trials. National and global CSOs can contribute to bridging this gap. Snapshot reviews of clinical trial sites developed by CSOs, such as a 2021 report by EATG, “Clinical Trial Sites in Eastern Europe and Central Asia HIV, Viral Hepatitis, Tuberculosis Brief Landscape Review,” can be developed by regional CABs with a focus on sites for TB vaccine research.<sup>38</sup>




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### **CSOs engage vaccine developers on the use of innovative trial designs within CRP discussions.**

Community representatives should be consulted on the use of innovative trial designs in CRP discussions. Some interviewees recommended that research plans include a comparison of TB vaccines with TPT and look at the efficacy of a strategy combining vaccination with TPT. To date, no clinical trial has been designed to compare a TB vaccine to TPT. Instead, most studies have opted to restrict TPT to PLHIV and require that this group complete TPT prior to randomization.<sup>39</sup> For trials comparing TPT and TB vaccines, experts noted that it might be difficult to demonstrate vaccine efficacy in high-risk groups taking TPT. None of the developers interviewed cited plans for direct TB vaccine and TPT comparisons in the context of clinical trials before licensure.

Clinical trials in which different TB vaccine candidates, especially of the same type, are compared against each other are of interest to some experts. However, this approach may risk early loss of candidates that may demonstrate sufficient safety and efficacy to reach the market at later stages. According to some vaccine developers, it may be better to conduct such trials in post-marketing research. Additionally, some experts are discussing the possibility of including trial endpoints that measure vaccine efficacy against asymptomatic TB.

CSOs have the capacity to provide insights regarding these and other innovative trial designs through CABs and raise awareness about the trials among communities near research sites.





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### Action 2

## Vaccine developers commit to meaningfully engaging communities and TB survivors in TB vaccine development as co-owners of the CRP.

Communities of people affected by TB should be considered co-owners of the TB vaccine development process rather than external stakeholders, as they represent either participants of clinical trials or direct beneficiaries of new TB vaccines. Routine CSO engagement should be an integral part of TB vaccine development. This engagement takes the form of implementing general and trial-specific community engagement plans, which should include:

- Trial protocol review by CABs before studies are launched
- Establishment and capacitation of CABs at trial sites
- Collaborations with local communities to ensure efficient trial enrollment
- Community participation in data and safety monitoring boards
- Regular communication between vaccine developers and global, regional, national, and local CABs about the clinical trial progress

#### Ideal scenario:

Developers work proactively with CSOs to create general and trial-specific community engagement plans as an integral part of CRPs, providing opportunities for communities to engage at each clinical trial stage. CSOs build their capacity in the field of clinical trials.

### **Vaccine developers involve affected communities and TB survivors in clinical trial protocol development, study implementation, and results dissemination.**

TB vaccine developers should adopt a combined, multilevel approach to community engagement based on a central community engagement plan and a budget for activities at the site level. Community engagement plans should include early and regular communication between vaccine developers and the Global TB CAB, regional CABs, and national CABs regarding trial design, progress, and plans for further trials.



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“Active engagement with the community at each trial site is essential – fostering consensus around the necessity of clinical trials and boosting the visibility of ongoing studies within the country. Such involvement ensures that the community not only understands the importance of participation but also becomes an advocate for the clinical research being conducted.”

CABs should regularly reach out to TB vaccine developers to foster relationships and dialogue.

Sharing trial protocols and community engagement plans with CSOs, trial site CABs, and regional and global CABs for feedback before the design is finalized stands out as an area for improvement. This is a long-standing practice in HIV drug development, resulting in more comprehensive, patient-centered research and paving the way for better access to treatment.<sup>40,41</sup>

### **CSOs build their capacity and the capacity of affected communities and TB survivors to engage in TB vaccine research.**

Enrollment in the phase III M72/AS01E trial was completed 11 months earlier than

expected, which was largely attributed to community engagement at the trial sites and the role of CABs in sharing information with communities.<sup>42</sup> This underscores the critical role of communities in research. To support and strengthen this role, investment in CSO capacity building at all levels is required, particularly at the trial site level. Key areas include general understanding of what participation in clinical trials implies and knowledge of clinical trial design. Examples of community capacity-building projects include TB training curriculums (e.g., CABLab), webinars, and the development and dissemination of community-friendly materials.

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### Action 3

#### CSOs communicate results of TB vaccine clinical trials widely at the global, regional, and national levels.

One of the key roles of CSOs is communicating information about research progress to a larger multi-stakeholder audience to pave the way for new TB vaccines. In many settings, CSOs are well positioned to disseminate the latest data among politicians, government officials, national TB programs (NTPs) and NIPs, health care professionals, and local communities.

#### **Ideal scenario:**

Information regarding the progress of TB vaccine research is disseminated to a broad and diverse range of stakeholders at all levels through CSO communication initiatives.

#### **CSOs hold vaccine developers accountable for transparently communicating research results to clinical trial participants, CAB members, affected community representatives, and other stakeholders.**

Vaccine developers must proactively and transparently share results from clinical trials with community representatives, starting with the trial participants. In a positive example of results sharing, investigators of former TB vaccine candidate H56:IC31 shared topline results, key messages, and preliminary analyses of safety and effi-

cacy outcomes with participants and site-level CABs first, and then with researchers, funders, global policy makers, and representatives of affected communities, before formally presenting at a scientific conference (CROI) in March 2024. In contrast, other sponsors have waited months after studies have ended to publicly share results, creating uncertainty about the success or failure of vaccine candidates (e.g., VPM1002). CABs and vaccine developers should define best practices for proactive communication, and CSOs should hold developers accountable for upholding these practices.

#### **CSOs ensure the latest publicly available clinical data reach the largest audience of stakeholders.**

Clinical data on TB vaccine development should be widely presented at global, regional, and international conferences and other TB-related events. All lung disease, immunization, and HIV-related conferences should have designated tracks for TB vaccine research. CSOs should advocate for specific sessions on TB vaccines in conference agendas.

CSOs should cooperate with the media to spread up-to-date and accurate information about TB vaccine research to the general public and disseminate relevant information to key stakeholders at the national level, including local communities, health care providers, NTPs, government officials, and policy makers.

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### Action 4

#### CSOs advocate for sustained and increased funding for TB vaccine research.

The annual \$5 billion funding target for TB research was endorsed by countries at the United Nations High-Level Meeting on TB in September 2023. Yet total spending on TB research reached only \$1.2 billion in 2023, a quarter of the target. Recent upheavals in U.S. policy will likely undermine TB vaccine research funding, especially given the U.S. National Institutes of Health's position as the largest funder of TB research. The full extent of disruptions to TB research funding will only become clear in time.

CSOs play a pivotal role in advocating for increased and sustained funding for TB research through public campaigns, targeted advocacy with donors and national governments, and TB research spending monitoring.

#### **Ideal scenario:**

New donors invest in TB vaccine development, including governments of middle-income countries, and total spending on TB vaccine research reaches the annual funding target of \$5 billion by 2028.

#### CSOs monitor TB vaccine research spending to create an evidence base for advocacy.

TAG regularly monitors global spending for TB vaccine research through an annual

global survey of TB research funders, the results of which are published in the *Tuberculosis Research Funding Trends* report series.<sup>45</sup> These data form an essential evidence base for advocating for increased and diversified funding for TB vaccines research. CSOs operating at the national level should adopt this practice by monitoring TB R&D expenditures by their governments.

#### CSOs advocate for sustained and increased funding for TB vaccine research provided by governments and other funders.

TAG, the Stop TB Partnership, and other advocates have called for governments to commit their fair share to TB research by allocating 0.15% of their total research spending to TB. According to TAG's *Tuberculosis Research Funding Trends* report, in 2023, only two countries met this target: South Africa and India. CSOs should scale up campaigns to persuade their governments to allocate more funding for TB research, especially in view of U.S. funding cuts. As TB vaccine R&D is heavily dependent on philanthropic support, domestic funding is critical to ensure funding sustainability.

During the United Nations High-Level Meeting on Tuberculosis in September 2023, member states adopted a new political declaration and agreed to convene a third United Nations High-Level Meeting in 2028 to review progress. CSOs should commence preparations for advocacy activities



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in advance of this meeting, beginning as early as 2026.

Members of CSOs who are formally integrated into the advisory or decision-making bodies of donor organizations are encouraged to advocate for funding allocations for TB vaccine research.

### **CSOs explore and propose new financing models for TB vaccine research to governments and funders.**

In the 2024 *Tuberculosis Research Funding Trends* report, TAG highlighted the need to diversify the TB research funding landscape to reduce dependency on traditional “mega-funders,” such as the U.S. National Institutes of Health and large philanthropic organizations that comprise a majority share of TB vaccine R&D funding (Gates, Wellcome, Open Philanthropy). Economic realities, such as high sovereign debt burdens, limit the ability of high-TB-burden nations to invest broadly in TB vaccines and underscore the need for new funding models in addition to new funding sources.

Some interviewed experts raised the idea of a TB vaccine research fund, which could serve as a platform for accumulating investments from different donors interested in investing in TB vaccine research. A joint fund could also support trials with head-to-head comparisons of different candidates that developers have been reluctant to initiate. This fund could be created and administrated under the United Nations system, for example, the WHO or Unitaid.

CSOs should shape conversations with governments and other funders about the feasibility of establishing innovative funding models for TB vaccine research and advocate for the implementation of impactful financing solutions for TB vaccine development and delivery.

### **Funders support CSO advocacy for and engagement in TB vaccine research.**

CSOs involved in TB efforts worldwide are calling for increased investment in community-led advocacy – such as the petition for a Fully Funded Challenge Facility for Civil Society.<sup>44</sup> It is essential that these appeals are addressed and supported, and engagement in TB research should be specifically highlighted in funding opportunities for civil society, including through dedicated tracks. CSO-led TB vaccine research activities can include:

- Policy dialogue with vaccine developers, the WHO, and funders through CABs to provide feedback on TB vaccine research
- Mapping and analysis of the TB vaccine clinical trial landscape or trials sites across regions
- Mapping of national regulatory frameworks in the field of vaccine development
- Engagement with developers to address challenges in TB vaccine research, particularly those related to the needs of key and vulnerable populations
- CSO capacity building around TB vaccine research



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The initial preparatory measures for TB vaccine implementation start with comprehensive multi-stakeholder consultations to systematically analyze factors critical to ensuring access. These include anticipated demand, manufacturing volumes, pricing strategies, potential intellectual property (IP) barriers, and licensing and technology transfer. Preparations also encompass consideration of normative and regulatory pathways to facilitate country-level availability. Budget advocacy begins at the same time to secure adequate funding from both donors and governments to procure sufficient vaccine quantities and raise the resources needed to deliver them.

### Action 5

CSOs contribute to the development and implementation of comprehensive product-agnostic and product-specific access policies for new TB vaccines.

Interviewees emphasized the importance of having multiple vaccines and suppliers available in the market to balance both purchasing and supply power. They also highlighted the need for geographically diverse manufacturing to ensure a resilient supply chain.

Several product-agnostic roadmaps for new TB vaccines have been developed by the WHO and other stakeholders including the *Global Framework*. The Finance and Access

Working Group of the WHO TB Vaccine Accelerator Council presented a report – *Catalyzing Solutions for Equitable Global Access and Sustainable Financing for Novel Tuberculosis Vaccines for Adults and Adolescents* – at South Africa’s G20 Summit in November 2025.<sup>45</sup> The report proposes strategic partnerships, financing and procurement mechanisms, and market access solutions, with a particular focus on speeding up vaccine access for high-TB-burden countries.

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As clinical research progresses and new data emerge, access policies will need to evolve. Product-specific policies should be developed by vaccine producers and external stakeholders, including CSOs. Vaccine developers and manufacturers should proactively make access policies public, transparent, and open to feedback from CSOs. Policies should offer clear access solutions for all country archetypes, including Gavi-eligible and self-procuring countries, with a focus on national regulatory approval timelines, manufacturing capacity, affordable pricing, licensing strategies, and IP management.

Some interviewees suggested moving away from the tiered-pricing approach in which Gavi-ineligible countries pay significantly more than Gavi-eligible countries, especially considering that several high-TB-burden countries (e.g., Brazil, Indonesia, India, and the Philippines) do not meet the Gavi eligibility criteria. One solution would be a flat-pricing model covering all low- and middle-income countries (LMICs) and high-TB-burden countries regardless of country income level.

CSOs have played an instrumental role in the development and implementation of access strategies across disease areas. This contribution is acknowledged by all principal public health stakeholders, including governments, UN agencies, pharmaceutical companies, and academic institutions.<sup>46</sup> CSOs have contributed to the development of TB vaccine access policies through their participation in the TB Vaccine Accelerator Council and its working groups. Their efforts have included the prepara-

tion of independent analytical papers and engagement with vaccine developers. These activities should expand, utilizing a broader array of tools and ensuring significantly wider representation from diverse affected communities.

### Ideal scenario:

Vaccine developers and funders publish comprehensive, transparent, and public access policies for new TB vaccines – both product agnostic and product specific – with input from CSOs, offering solutions to maximize access to new TB vaccines in all countries.

### CSOs develop recommendations for TB vaccine access policies, informed by input from a diverse range of key community groups.

The role of civil society in influencing access policies should encompass the following domains:

- Time-bound access solutions for all countries
- Cost of goods and price estimates informed by independent research with a push toward adoption of flat-rate prices close to production costs for as many countries as possible
- Demand estimates for different countries, including key groups and the general population
- IP, licensing, and technology transfer policies with a focus on identifying and

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“ If a TB vaccine is introduced, it is crucial that civil society advocates for abandoning tiered pricing in favor of a flat-rate model aligned with production costs. This equitable approach can be realized through guaranteed purchase volumes, ensuring fair access for all. ”

mitigating potential barriers

- Procurement and supply solutions designed to maximize and expedite access to populations most in need
- Access considerations for key groups (e.g., PLHIV, people living with diabetes, people using drugs, migrants, prisoners)

Policy recommendations may be presented as policy briefs or research reports, including peer-reviewed studies, and may serve as resources for further advocacy initiatives. As vaccine candidates near market, it will be essential for civil society to develop tailored access strategies that consider the unique characteristics of each candidate.

### **CSOs share community access recommendations with decision makers by engaging in multi-stakeholder consultations on TB vaccine access policies at all levels.**

Several multi-stakeholder mechanisms are available for CSOs to influence TB vaccine

access policies across all levels: TB Vaccine Accelerator Council working groups, Gavi CSO Constituency, Communities Delegations to the Global Fund and Unitaid Boards.

To elevate the issue of TB vaccine access to the highest political forums, civil society should leverage major global and regional events, such as the UN High-Level Meetings, G7 and G20 summits, BRICS forums, and other regional political platforms.

CSOs may further advance the cause of equitable access to TB vaccines by actively engaging key stakeholders through CABs, targeting vaccine manufacturers and distributors, donor agencies, UN agencies, and government representatives at political, technical, and scientific forums.

Community consultations concerning access policies should solicit input from all key groups of people who need new TB vaccines. Engaging key populations ensures that policies are equitable, responsive, and reflective of the needs of those most affected.



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### Action 6

#### WHO and other normative bodies consult CSOs on policy formation and product review.

**G**lobal policy recommendations for new TB vaccines will be set by the Strategic Advisory Group of Experts on Immunization (SAGE) at the WHO. SAGE is responsible for advising WHO on global policy and strategies related to immunization. Their advice informs everything from vaccine research and development, immunization delivery, and vaccine prioritization for the WHO prequalification process.

Financing by Gavi and procurement by UNICEF and the Pan American Health Organization Revolving Fund are dependent on SAGE policy recommendation and WHO prequalification. Countries that procure vaccines with Gavi support must purchase WHO prequalified products or vaccines for which compliance is assured by fully functional national regulatory authorities (NRAs).<sup>47</sup>

SAGE meetings in March 2023 and September 2025 have featured conversations about new TB vaccines, research plans, and considerations for a potential introduction.<sup>48,49</sup> At the group's September 2025 meeting, members discussed candidates in late-stage clinical development and issues related to the

availability of vaccine efficacy data in persons with and without *Mycobacterium tuberculosis* infection and the potential incorporation of asymptomatic TB into clinical trial endpoints. WHO has also established a Technical Advisory Group on Evidence for Clinical and Policy Considerations for New Tuberculosis Vaccines, whose objectives include providing independent advice to WHO and SAGE related to scientific, clinical, regulatory, and policy dimensions of new TB vaccine candidates.<sup>50</sup>

The WHO Vaccines Prequalification Priority List for 2024–2026 includes BCG as a medium-priority vaccine for prequalification. Other TB vaccines fall under the category of “Potential candidate vaccines to be considered during the biennium if development is completed and address public health needs.” Manufacturers are encouraged to apply for prequalification of vaccines if they meet key criteria.<sup>51</sup> In many jurisdictions, WHO prequalification is a criterion for accelerated and/or simplified regulatory approval procedures (as shown in the country policy portraits).

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### **Ideal scenario:**

New TB vaccines are designated as high-priority products for WHO prequalification, and the WHO involves CSOs in policy-making and technical advisory processes.

### **The WHO strengthens engagement with CSOs in SAGE policy development.**

Formal CSO participation in SAGE is currently minimal. The WHO can invite observers to SAGE meetings, including members of civil society.<sup>52</sup> CSOs are encouraged to engage with SAGE and provide feedback to inform TB vaccine policy and updates to the vaccine prequalification priority list. In turn, SAGE should place more focus on collecting feedback from CSOs by establishing a channel for communication with civil society.

This collaboration should enable CSOs to increase the visibility of SAGE recommendations across the globe, including in self-procuring countries, which may not always look first to SAGE recommendations for vaccine introduction.

### **CSOs maintain proactive engagement with vaccine manufacturers to ensure the prioritization of expedited WHO prequalification.**

Plans regarding WHO prequalification should be systematically included in agendas for all CAB meetings and written correspondence with potential vaccine manufacturers. CSOs should share timely information on WHO prequalification status with all relevant stakeholders, including national governments. This is particularly important in countries where expedited approval processes based on WHO prequalification are applicable.

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### Action 7

CSOs advocate for timely national approval of TB vaccines by governments and broad regulatory filings by vaccine developers and manufacturers.

Securing national regulatory approval is essential to ensure sustainable access to novel TB vaccines, and, in many jurisdictions, approval is a prerequisite for vaccine inclusion in the NIP. Several pathways can be utilized to more efficiently obtain marketing authorizations for new TB vaccines:

- Simplified and accelerated national approval procedures for WHO-prequalified products or products approved by stringent regulatory authorities (SRAs), including via the WHO Collaborative Registration Procedure.
- The EU-M4all mechanism, used by the European Medicines Agency (EMA), assesses innovative or generic medicines and vaccines that address unmet medical needs or are of major public health interest, for use outside the European Union.<sup>53</sup> The EMA PRIME Scheme is another mechanism used by the EMA to enhance support for the development of health products that target an unmet medical need.<sup>54</sup>
- Regional approval procedures to facilitate national approval in smaller markets (e.g., medicines and vaccines approval under the rules of the Eurasian Economic Union; see the Kazakhstan country policy portrait).
- Some countries may require local clinical trials as a prerequisite for approval, which can delay marketing authorization if licensure trials are not geographically inclusive.

#### Ideal scenario:

Developers and manufacturers have a public and proactive regulatory approval plan for all countries, considering opportunities for accelerated and simplified procedures, collaborative registration initiatives, and extra requirements for national approval, such as local clinical trials. Developers and manufacturers follow this plan and are open to feedback from CSOs about issues related to the vaccine approval process.

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### **CSOs analyze approval requirements for TB vaccines and monitor the vaccine approval landscape.**

Mapping national approval frameworks for medicines and diagnostics related to HIV, HCV, TB, and other diseases has long constituted an area of expertise for civil society. CSOs at the regional and national levels should analyze procedures for country approval of new TB vaccines, with a focus on the following parameters:

- Applicability of regional collaborative approval mechanisms
- Timelines and fees for approvals
- Key documents needed for the dossier
- Availability of fast-track approval and prerequisites
- Requirements for local clinical data to obtain national approval
- Opportunities for supplying vaccines without national approval (e.g., import waivers for vaccines procured through Gavi, Global Fund, or UNICEF)

Once developers file new TB vaccines for WHO prequalification and/or SRA approval, CSOs should commence monitoring the

national approval status of these vaccines. This information should be utilized in communications with vaccine manufacturers and other stakeholders to facilitate the approval process and create accountability for timely registration.

### **Vaccine developers and manufacturers work with CSOs to support national approval of TB vaccines.**

Regional and national CSOs and CABs possess substantial experience in offering consultative support to pharmaceutical companies regarding procedures for medicines approval. Their expertise includes identifying potential obstacles, recommending optimal regulatory pathways, and facilitating communication between regulatory agencies and pharmaceutical companies. For instance, engaging with pharmaceutical companies and other treatment access stakeholders to discuss national approval procedures is a key priority for the Eurasian Community for Access to Treatment (ECAT). It is recommended that CABs at all levels incorporate national approval into meeting agendas with vaccine manufacturers and other stakeholders.



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### Action 8

**Governments strengthen relationships with CSOs to facilitate the integration of new TB vaccines into national health programs.**

**N**ew TB vaccines may be integrated into national health systems at various levels, from demonstration projects targeting key populations in specific regions to full integration in NIPs. The process requires the involvement of diverse stakeholders, including ministries of health; national TB, HIV, immunization, and harm reduction programs; ministries of education; penitentiary services; NITAGs; and CSOs.

Unlike infant and childhood vaccines, rolling out TB vaccines for adults and adolescents will require new platforms and infrastructure – likely leading to higher costs and increased logistical complexity. However, for certain cohorts – such as PLHIV or people with diabetes – implementation may be possible through integration with existing primary care systems.

There must be a coordination mechanism that brings together all relevant services based on the target groups, and CSOs should play a central role within this mechanism.

#### **Ideal scenario:**

By 2030, assuming new TB vaccines demonstrate adequate efficacy and safety, countries will have incorporated the vaccines into NIPs and will have initiated demonstration projects with civil society involvement, including CSO participation in NITAG processes.

#### **NITAGs invite CSOs to participate in vaccine review and policy making.**

NITAGs play an indispensable role in decisions to include vaccines in NIPs. However, as the country policy portraits in section two illustrate, most NITAGs do not formally incorporate civil society representatives as voting members, and not all hold public meetings or share minutes afterward. NITAGs appear to have largely underestimated the contributions CSOs can make to vaccine policy making.



## Delivery Action Plan

Strengthening connections between CSOs and NITAGs is a key priority. CSOs are strategically positioned to conduct proactive analyses of national requirements for the integration of new TB vaccines into national immunization plans. Additionally, CSOs can facilitate dialogues among national stakeholders, vaccine manufacturers, donors, and technical partners about vaccine introduction.

### **Governments invite CSOs to participate in multi-stakeholder consultations regarding the integration of TB vaccines in national health care systems.**

Government agencies, including NITAGs, NIPs, and NTPs, should invite CSOs to participate in TB vaccine policy making, both directly and through multi-stakeholder platforms. In this context, UN agencies such as the WHO and donor organizations, including the Global Fund and Gavi, should serve as mediators to facilitate these collaborations. Community groups are also encouraged to participate in country-level TB vaccine preparedness workshops organized by the WHO TB Vaccine Accelerator Council, like those organized in Indonesia and South Africa.<sup>55,56</sup>

### **Governments involve CSOs in new TB vaccine introduction and implementation at the national level.**

Demonstration projects may constitute a crucial preliminary phase in the introduction of a new vaccine prior to full inclusion in the NIP. Some countries may opt to introduce new vaccines in limited settings due to constrained funding, supply limitations, or the need to prioritize specific target groups. CSOs should play an integral role in this process by identifying priority populations and geographic areas, facilitating enrollment and retention, and advocating for the transition from demonstration projects to national programs. Governments should invite CSOs to inform the design and direction of TB vaccine implementation and support community-based organizations in vaccine delivery.

NTPs also have an important role to play. Vaccination may be less of a priority for NTPs due to limited budgets, lack of experience dealing with vaccines, and existing programmatic priorities. It will be important for NTPs to proactively determine where vaccines should be positioned within existing prevention strategies, particularly TPT programs. CSOs can assist NTPs by providing consultative support and acting as a bridge between health care programs and communities (see also Demand).

## Delivery Action Plan

### Action 9

#### CSOs intervene to promote sustainable manufacturing, procurement, and supply of new TB vaccines.

CSOs are universally recognized as key stakeholders in ensuring adequate, equitable, and sustainable access to treatment, from manufacturing to delivery. They employ a variety of tools, including direct negotiations, multi-stakeholder dialogue meetings, advocacy and awareness-raising campaigns, and targeted access interventions such as challenging IP barriers.

The product-agnostic and product-specific policies mentioned previously should provide the foundation for CSO-led activities related to manufacturing, procurement, and supply, underpinned by a clear vision for access.

#### **Ideal scenario:**

CSOs independently and collaboratively intervene to expedite and maximize access to new TB vaccines through enhanced manufacturing, procurement, and supply.

#### **Vaccine developers identify commercial partners prior to launching phase III trials, and CSOs hold developers accountable for early access planning.**

To pave the way for vaccine rollout, it is essential that the identification of and

engagement with commercial partners remains a permanent fixture on the agenda whenever CSOs interact with TB vaccine developers and funders. For candidates in later development stages, this should commence before 2028, and for earlier-stage candidates, between 2028 and 2029.

The M72/AS01E vaccine is furthest along in clinical trials, with its phase III trial fully enrolled. But as of early December 2025, the developers had not yet announced a commercial partner and marketing authorization holder. There are three commercial partners for MTBVAC, including Biofabri (Spain), Bharat Biotech (India), and FAP (Fundação Ataulpho de Paiva, Brazil), responsible for different geographic areas. Negotiations with potential partners for BNT164 are expected once the phase II trials have demonstrated sufficient efficacy and safety for advancing the vaccine candidate to phase III.

It is advisable that CSOs, particularly those operating on the global stage and with deep expertise in access work, prioritize this issue when engaging with vaccine developers.

#### **CSOs research and uncover potential challenges to sustainable manufacturing, procurement, and supply of new TB vaccines.**

CSOs are uniquely positioned to conduct independent research on TB vaccine access,



## Delivery Action Plan

“**T**here is a perception within the TB community that patents are not a concern. However, patents will undoubtedly become an issue [for] new TB vaccines. Numerous patents and applications exist, including in countries with manufacturing capacity, and companies are fighting with each other [over] IP rights. The landscape for vaccine IP is considerably more complex than for drugs, and substantial capacity building is needed to involve communities in IP-related work to ensure equitable access to new TB vaccines.”

reinforcing broader efforts to enhance treatment availability in the fight against TB. Moreover, they can actively support studies spearheaded by partners such as the TB Vaccine Accelerator Council, Gavi, the Working Group on TB Vaccines, and others.

The following areas of research related to access can be pursued by CSOs:

### **Manufacturing:**

Factors pertaining to manufacturing include requirements based on vaccine types and individual vaccine characteristics (mRNA, live attenuated, whole cell, etc.), including the need for specific ingredients (such as AS01 adjuvant for M72/AS01E), timelines for scaling up manufacturing, and potential manufacturing sites. Interviewees expressed particular concern regarding the availability of AS01, citing factors such as limited man-

ufacturing capacity – especially since it is used in other vaccines and a key component relies on sourcing from the natural world – and potential challenges related to intellectual property.

mRNA vaccines have been characterized as easier to produce compared to traditional vaccines, because the manufacturing process involves routine biochemistry, whereas traditional vaccines rely on biology and cell-based components.<sup>57</sup> An analysis from MSF shows that there are many companies across Africa, Asia, and Latin America capable of producing mRNA vaccines.<sup>58</sup> Research by CSOs could also explore opportunities for leveraging mechanisms such as the WHO mRNA Technology Transfer Hub<sup>59</sup> and Gavi’s African Vaccine Manufacturing Accelerator (AVMA)<sup>60</sup> to support sustainable growth of Africa’s manufacturing base.<sup>61</sup>

## Delivery Action Plan

### Pricing:

As demonstrated by the WHO list of vaccine prices and the PAHO price list, most widely used vaccines rarely exceed US\$1 per dose, due to the immense economies of scale in their production.<sup>62,63</sup>

CSOs have actively contributed to research on prices for TB treatments and diagnostics. Examples include “Estimated generic prices for novel treatments for drug-resistant tuberculosis”<sup>64</sup> and calculations behind advocacy by the Time for \$5 campaign to lower the prices for GeneXpert tests.<sup>65</sup> Estimated prices can be compared to actual market prices for new TB vaccines in routine price monitoring and analysis, with substantial discrepancies flagged for advocacy. CSOs possess extensive expertise in price monitoring for medicines, diagnostics, and vaccines and have uncovered notable price disparities between countries. To ensure the affordability of new TB vaccines, it is essential that CSOs and independent experts are empowered with adequate resources to undertake price monitoring and analysis. CSOs should be at the forefront of initiatives to lower the cost of TB vaccines through evidence-based advocacy campaigns.

### IP and licensing:

Comprehensive analyses of IP and licensing landscapes are crucial, as these factors shape both the availability and affordability of TB vaccines. The Make Medicines Affordable campaign has prepared a landscape of patents covering M72/AS01E and MTB-VAC.<sup>66</sup> Similar patent landscapes should be

produced for mRNA-based TB vaccines and other promising candidates. Conducting freedom-to-operate analyses for new TB vaccines is essential to minimize IP risks for any company willing to manufacture these vaccines. CSOs can collaborate with external stakeholders on open-source databases for TB vaccine patents, similar to VaxPal.

### Procurement and supply mechanisms:

Countries can generally be classified into two groups: those eligible for Gavi support and those that procure vaccines independently (self-procuring). Gavi-eligible countries benefit from international procurement mechanisms (e.g., UNICEF) and Gavi support in managing vaccine supply chains.<sup>67,68,69</sup> Including new TB vaccines in the respective procurement catalogues once they are approved is a required step towards securing access to these vaccines.

For self-procuring countries, CSOs should proactively conduct research into national procurement requirements. Within established methodologies for analyzing procurement for pharmaceuticals and diagnostics, the following factors may be considered:

- Provisions enabling procurement of unregistered drugs/vaccines
- The need for a drug/vaccine to be included on special lists if procured using government funding (e.g., Essential Medicines List)
- Preferences for local manufacturers

## Delivery Action Plan

- Centralized (state-level) vs decentralized (provincial-level) procurement and designated agencies responsible for procurement
- Tender timelines, number of bidders, and calculations for initial tender prices
- Requirements for calculating the volume to be procured
- Transparency of the procurement process

Analyses could also assess distributor capacities to deliver new TB vaccines considering transportation and storage requirements to ensure supply sustainability country wide.

### Market shaping:

CSOs should track countries where new TB vaccines have been approved and incorporated into national health care systems. This tracking should assess current volumes and pricing, map out the suppliers and distributors involved, and determine whether actual or potential supply shortages exist. Previous research conducted by the WHO on the BCG vaccine highlighted risk factors such as the limited number of suppliers, outdated manufacturing processes, and the scarcity of registered products in certain countries.<sup>70</sup> A notable recent example of where market monopolies have led to supply shortages of life-saving vaccines is cholera.<sup>71</sup> These findings underscore the importance of evaluating similar risks for new TB vaccines – especially the M72/AS01E vaccine with known adjuvant supply monopoly concerns.

### CSOs intervene to improve access to TB vaccines across manufacturing, procurement, and supply chains.

Civil society possesses an array of tools to confront access barriers and advance practical solutions for improved vaccine availability. These strategies include opposing unjustified patents, guided by patent landscape analyses. Another would be campaigning for government use and compulsory licensing to enable domestic manufacturing, for example, by invoking local working requirements (national patent law rules that patents should be “worked” domestically to be enforceable). In the campaign to increase access to bedaquiline, CSOs collaborated with a diverse range of stakeholders in advocacy and patent opposition activities.<sup>72</sup> These coordinated actions led to the revocation of some patents and led the company to announce it would not enforce its secondary patents on bedaquiline.<sup>73</sup> As a result, access to generic versions of the medication has expanded globally, leading to lower prices and improved availability.

Civil society can further facilitate price-volume negotiations between purchasers and vaccine suppliers and advocate for multicountry pooled procurement to expand market size and enhance bargaining power. Additionally, encouraging governments to leverage international procurement agencies to pool demand and secure the lowest global prices represents another approach to ensuring equitable access.



## Delivery Action Plan

### Action 10

#### CSOs advocate for sustainable funding for the introduction and rollout of new TB vaccines.

The allocation of adequate funding constitutes an essential prerequisite for the introduction and deployment of new TB vaccines. This encompasses not only the financial resources necessary for vaccine procurement but also for vaccine distribution. The two principal stakeholder groups involved in this are governments and donor organizations, with Gavi and the Global Fund playing particularly prominent roles.

Interviewees pointed to several potential challenges to sustainable funding. First, the crisis resulting from retrenchment in U.S. foreign aid policy may constrain donor funding for new TB vaccine rollout. Second, the introduction of new TB vaccines entails upfront expenditures by NTPs and NIPs, as these vaccines will supplement, not replace, existing TB prevention strategies. A November 2025 report from the WHO TB Vaccine Accelerator Council Finance and Access working group modeled a “high demand scenario” that assumes a need for one billion TB vaccine regimens globally between 2030 and 2040 (up to 120 million regimens annually in the first five years after introduction) and estimated global procurement costs between US\$5 billion to US\$8 billion.<sup>74</sup> Future cost savings from diverted treatment and other averted health care systems costs will take time to accrue.<sup>75</sup>

Moreover, there will be additional costs associated with establishing vaccination infrastructure for adults and adolescents. Some countries may be reluctant to assume additional financial burdens unless clear cost-efficiency benefits are demonstrated.

CSOs are well positioned to advocate for funding to procure vaccines, hold governments and donors accountable by tracking expenditure levels, and identify opportunities for optimizing spending without compromising access.

#### **Ideal scenario:**

CSOs are resourced to advocate for sustainable financing of new TB vaccines. Building upon their established influence and capabilities, CSOs act as both advocates and watchdogs, ensuring transparency, equity, and efficiency of expenditure throughout the vaccine rollout process.

#### **CSOs assess potential and actual levels of spending on new TB vaccines.**

CSOs operating at the national level are encouraged to track TB vaccine expenditures by their governments. Building off ongoing monitoring of global TB research



## Delivery Action Plan

expenditures by TAG (see Development), analogous reports can be regularly produced as new TB vaccines become available. Monitoring efforts will be vital for informing advocacy for increased, diversified, and innovative financing for TB vaccines. Combined with vaccine demand estimates, these reports can also set targets for TB vaccine spending at both global and country levels.

TB vaccine resource tracking may be incorporated into broader research concerning vaccine manufacturing, procurement, and supply.

### **CSOs push donors and governments to allocate sufficient funding for new TB vaccines.**

CSOs should serve as liaisons between affected communities, governments, and donors using existing consultative forums and advocacy campaigns. The agenda for these consultations will include key items: estimated demand based on vaccine characteristics and epidemiology, currently available products with prices and manufacturing capacity, currently available level of donor and government spending by country and financial gaps to be filled, opportunities for procurement optimization and price reductions, and cost-efficiency analyses and investment cases for new TB vaccines.

Examples of stakeholder engagement to bolster funding for new TB vaccines include hosting parliamentary hearings prior to

national budget discussions and leveraging global advocacy campaigns to send messages to governments and donors about the need to invest in vaccine readiness and immunization infrastructure.

### **Funders, governments, and multilateral agencies invest in community-led TB vaccine access interventions.**

CSO interventions will be key to ensuring adequate and sustainable access to TB vaccines. However, there is a lack of dedicated resources for CSO activities.

In 2021, Gavi determined that 10% of the total country funding envelope should be reserved for CSOs. However, interviewees noted that it can be challenging to guarantee that a portion of this 10% CSO set aside supports advocacy activities, as governments may be reluctant to fund initiatives that scrutinize their own performance.

A commitment from donors to sustainably allocate funding to CSO-led access activities for new TB vaccines is critical. CSOs can contribute by engaging with key constituencies on the Stop TB Partnership, Gavi, and Global Fund boards. CSOs should also advocate for the inclusion of CSO-led access interventions in Gavi and Global Fund country proposals. When considering funding for access initiatives from the commercial sector, it is essential to address and mitigate potential conflicts of interest.



## Demand Action Plan

**Demand for the new TB vaccines will be driven by several factors: the target population being adults and adolescents, key groups prioritized for vaccination, the extent to which new TB vaccines are integrated into existing prevention strategies, the availability of financing as international aid budgets shrink, crowded immunization schedules, and the geographical distribution of the TB disease burden (i.e., large disease burden in middle-income countries that are not Gavi eligible).**

A report by the WHO TB Vaccine Accelerator Council Finance and Access Working Group projects that the initial launch of TB vaccines under a “high demand scenario” will require a minimum of 50 million full vaccine regimens, peaking around 120 million regimens within the first five years of availability and settling around 90 million annually in the subsequent five years. This scenario balances ambition with feasibility though other scenarios are modeled.<sup>76</sup>

Two primary vaccine deployment strategies are under consideration: mass campaigns targeting the general population aged 15–45, and risk-

based approaches prioritizing specific high-risk groups. National prioritization will vary according to epidemiology, financial constraints, sociocultural context, and vaccine supply, which in turn influences procurement volumes. The report assesses that under a “high supply scenario,” reflecting optimistic licensure and manufacturing outcomes, the annual number of regimens produced will start around 20 million in 2030, scaling to 60 million mid-decade, before increasing to 160 million regimens by 2040. This means that global demand for TB vaccines will outpace supply in the critical early years of introductions in the absence of corrective intervention.



## Demand Action Plan

### Action 11

#### CSOs participate in multi-stakeholder consultations to estimate and build upfront demand for new TB vaccines.

The WHO Global Framework identifies CSOs as key stakeholders in demand forecasting, communication, implementation, and delivery. CSO involvement is essential in defining, advocating for, and mobilizing demand among vulnerable groups, many of whom may be more effectively reached by CSOs than by government entities. CSOs at all levels can contribute to demand planning by participating in multi-stakeholder exercises to produce demand estimates globally, regionally, and nationally. Utilizing information from community-led research and monitoring, CSOs are also positioned to influence decision making around priority populations, to advocate for price-volume negotiations with funders and vaccine manufacturers, to evaluate the extent to which modeled estimates of demand materialize (or not), and to propose solutions for overcoming barriers to converting potential demand into “shots into arms” – especially in the face of constricted vaccine supply.

#### **Ideal scenario:**

Sustained collaboration among CSOs, funders, UN agencies, governments, disease programs, and manufacturers results in market-shaping interventions that ensure adequate availability and affordability of the first new TB vaccines to reach market.

#### **CSOs participate in national consultations to estimate the number of people eligible for new TB vaccines.**

Preliminary demand estimates should be prepared for each vaccine candidate approaching approval, complementing global demand projections and based on the latest clinical data, starting between 2025 and 2027 for current late-stage candidates (M72/AS01E, MTBVAC). Demand estimates may be derived from official government sources or from independent expert assessments and informed by CLM



## Demand Action Plan

initiatives. CSOs have engaged in similar efforts to advance novel all-oral treatment regimens for drug-resistant TB and short-course TPT, providing a valuable foundation for generating demand for new TB vaccines.

There should be dedicated meetings at the global, regional, and national levels to coordinate demand creation activities among stakeholders and between countries, vaccine purchasers, vaccine developers and manufacturers, funders, and CSOs.

### **CSOs influence demand-based negotiations with manufacturers and advocate for fair price-volume agreements.**

The demand estimates put forward by the WHO TB Vaccine Accelerator Council Finance and Access Working Group will serve as the foundation for negotiating access conditions with TB vaccine manufacturers. These negotiations are expected to culminate in price-volume agreements between vaccine producers, funding organizations, procurement agencies, technical partners such as UN agencies, and governments.

During these negotiations, CSOs should advance principles of equitable access and establish clear conditions and red lines regarding key elements of the agreements. This includes advocating for transparency in areas such as the cost of goods and services, pricing structures, and regulatory approval timelines. Furthermore, CSOs should call for technology transfer to facilitate regional and local vaccine production and support the implementation of fair pricing policies.

In addition, CSOs have a crucial role in raising awareness about the estimated need for, and the importance of access to, new TB vaccines – particularly among priority populations. They should monitor and influence negotiations with vaccine manufacturers to ensure that the greatest possible number of countries benefit from the resulting agreements and that the proposed prices closely align with the lowest estimated costs for large-scale procurement based on objective, transparent criteria such as COGs+ tied to volumes sold (see Delivery).

## Demand Action Plan

### Action 12

#### CSOs organize vaccine preparedness and demand promotion interventions for new TB vaccines in communities.

Within the broader remit of vaccine preparedness, demand creation is fundamental to achieving access. Stakeholders responsible for introducing new vaccines and executing immunization programs should invest in these activities. Many of these initiatives can be supported or directly implemented by CSOs.

UNICEF's *Demand for Health Services: A Human-Centred Field Guide for Investigating and Responding to Challenges* emphasizes the importance of involving end users and communities in designing health services to ensure that solutions are effective and contextually relevant.<sup>77</sup> The recommended approach supports a bottom-up methodology rooted in community engagement and encourages local definition and development of problems and solutions. Tuberculosis-specific resources should be created to design demand promotion strategies for new TB vaccines.

The Rockefeller Foundation's *Infrastructures of Trust: The Case for Investing in Vaccine Demand* advocates for shifting away from traditional vaccine hesitancy frameworks, asserting that such models misattribute and reduce the responsibility for vaccination to individual motivations and access.<sup>78</sup> The report calls for broadening the conceptual framework and investing substantially in vaccine demand, a perspective that

recognizes the influence of institutional and structural determinants of vaccine uptake, alongside individual drivers. The report frames vaccine demand as a society-wide challenge that necessitates significant investment in human resources and programs. It also requires policy and regulatory adjustments, as well as a sustained commitment to building trust, enhancing health equity, and fulfilling the information needs of diverse communities.

#### Ideal scenario:

Product-agnostic and product-specific interventions to build demand for new TB vaccines are developed and implemented on a rolling basis with the involvement of CSOs at all levels. These frameworks look beyond vaccine hesitancy models to consider institutional and structural drivers of vaccine demand.

#### **Multilateral agencies (WHO, Gavi, Global Fund) and other stakeholders, including CSOs, develop product-agnostic and product-specific guidance for demand creation interventions.**

The WHO Global Framework provides a foundation for the development of further guidance aimed at generating demand



## Demand Action Plan

for new TB vaccines as they move toward approval. CSOs can play a critical role in guidance development by offering feedback within their subject-matter expertise, tailoring global guidance to local contexts, disseminating guidance among key national stakeholders, and ensuring translation into national policies. Furthermore, CSOs should collaborate with funders, vaccine developers, UN agencies, and government programs to formulate comprehensive frameworks for capacity building and demand generation related to new TB vaccines. These frameworks should draw upon existing tools and resources developed for other vaccines, including the WHO's 2021 demand planning tools for COVID-19 vaccines<sup>79</sup> and UNICEF's 2024 guide on demand promotion for HPV vaccination.<sup>80</sup>

As TB vaccine candidates receive approval, CSOs should work with relevant stakeholders to develop dynamic, product-specific guidance documents. These should provide detailed information on the key features of the approved vaccines, summarize SAGE recommendations, indicate national approvals and WHO prequalification status, and include data on suppliers, pricing, and requirements for transportation and storage.

### **CSOs implement local demand promotion and vaccine preparedness interventions.**

CSOs are expected to play a pivotal role in demand promotion and capacity building at the national level, serving as facilitators in dialogues between international partners and national stakeholders.

A key intervention to promote vaccine preparedness and demand generation includes convening multi-stakeholder meetings with government officials to generate political commitment for new TB vaccine introduction. Training programs for health care providers and community groups are essential to optimize the effectiveness of immunization initiatives, and targeted information campaigns can ensure that crucial messages about new vaccines reach priority audiences. More specific interventions may include advocacy for the establishment of national vaccine preparedness programs within ministries of health or the provision of technical support to NTPs for integrating adult and adolescent TB vaccination into existing service delivery systems. Strengthening the connections between communities and health policy makers from NITAGs, NTPs, and NIPs will further contribute to demand generation and effective implementation.

A careful analysis of previous access campaigns in the TB field is essential to identify best practices and areas for improvement. Experiences from advocacy campaigns to promote access to shorter TB treatments (1/4/6x24),<sup>81</sup> or increase TB funding (TB33% Campaign),<sup>82</sup> must be analyzed to understand what can be immediately adopted versus what must be adapted for new TB vaccines to ensure more effective introduction.

### **CSOs organize campaigns to communicate information about new TB vaccines.**

One of the principal challenges confronting the introduction of new TB vaccines is vac-

## Demand Action Plan

cine hesitancy. Hesitancy encompasses both a general mistrust of vaccines and specific concerns regarding new TB vaccines, particularly as most individuals will already have received the BCG vaccine. Accordingly, considerable effort is required to communicate the necessity of additional TB vaccination and to address more generalized public concerns about new vaccines to promote vaccine uptake among intended beneficiaries. As discourse around vaccines can become politically charged, it is imperative that data supporting vaccine introduction are robust and evidence based.

CSOs can play a significant role by contributing to vaccine preparedness and demand creation frameworks established by key stakeholders or by developing their own frameworks. Collaboration between TB-affected communities and target groups is essential to ensure that the needs of all key populations are adequately reflected.

Recent campaigns that sought to maximize access to novel TB prevention and treatment regimens can serve as valuable references. Learning from past campaigns, future campaigns should include tailored subcomponents for distinct stakeholder groups and operate on an ongoing basis. Sustained and continuous engagement is critical for long-term success, as time-limited campaigns are likely to be less effective against persistent vaccine denialism. Ultimately, the goal is to foster enduring public support for vaccines.

Campaigns related to new TB vaccines should, at a minimum, convey the following information:

- Essential data on vaccine safety, efficacy, and mechanism of action
- Clear information on vaccine administration procedures
- Populations that will benefit from vaccination
- Rationale for focusing vaccination on adults and adolescents
- Discussion of how new vaccines differ from and complement existing TB prevention interventions, such as TPT and BCG vaccination
- Factsheets debunking common myths about vaccines, including those specific to certain vaccine technologies (e.g., live attenuated [MTBVAC] or mRNA [BNT164] vaccines)

Campaigns should be adaptable to different key audiences. Engaging diverse audiences will require collaboration with trusted messengers. For example, CAB representatives who have witnessed TB vaccine trials firsthand and are invested in the science can serve as early ambassadors, effectively communicating the benefits of vaccination to their communities. Cross-sectoral coordination between government agencies will be paramount, including between those responsible for health, social welfare, education, culture, defense, and criminal justice.

International immunization initiatives, such as World Immunization Week and the Zero-Dose Campaign, can be adapted to support TB vaccination efforts. World Tuberculosis Day also presents a strategic opportunity to amplify awareness and promote the importance of TB vaccination.

## Demand Action Plan

### Action 13

#### Funders and governments invest in community-led vaccine preparedness and demand promotion interventions.

One of the key messages from interviewees concerned the need for additional financial resources for CSOs, so that they can play a leading role in national vaccine preparedness and demand promotion, bridging the gap between global guidance and national implementation.

Community-led vaccine preparedness and demand promotion interventions should be included as a priority area for both government-led and donor-led funding initiatives to support new TB vaccine introduction. CSOs should proactively develop and propose community-led demand creation interventions adapted to the national context and needs of specific communities and key groups.

#### **Ideal scenario:**

Funders include vaccine preparedness and demand promotion activities in calls for proposals and support community-led interventions across the globe; governments work with CSOs on vaccine preparedness and demand promotion interventions.

#### **Funders establish programs supporting community-led vaccine preparedness and demand promotion activities.**

Donors should establish flexible funding programs to support a variety of community-led vaccine preparedness and demand promotion interventions, as well as directly fund CSO-led interventions related to TB vaccination. Funders should consult CSOs in the development of grant programs to tailor opportunities for local context and needs. The first section of this report contains detailed recommendations on how to resource CSOs with examples of different funding models.

#### **CSOs develop and propose projects to build demand for new TB vaccines.**

Community-led vaccine preparedness and demand promotion projects can include:

- Research to estimate demand for TB vaccines in key populations
- Communication campaigns/information materials for key populations
- Outreach to refer member of key groups to TB vaccination programs
- Capacity-building trainings for community-based organizations
- Trainings for health care workers
- Budget advocacy



## Data Action Plan

**Monitoring and evaluation are integral to vaccine access. Data generation has been identified as a fourth, cross-cutting domain that, with *Development, Delivery, and Demand*, comprises a 4D view of access.**

This section of the roadmap centers community-led monitoring interventions to identify gaps in TB vaccine development, delivery, and demand creation. Data gathered through CLM can guide policies touching all dimensions of TB vaccine access. These efforts supplement monitoring and evaluation by governments, companies, funders, UN agencies, and other stakeholders.

Evidence shows that CLM improves the effectiveness, quality, and accessibility of health programs and empowers affected communities by enabling them to demand high-quality services.<sup>83</sup> According to the Stop TB Partnership, CLM helps identify systemic gaps and trigger action at the local, national,

and global levels.<sup>84</sup> The Gavi evidence brief “Community-based monitoring: Evidence on pro-equity interventions to improve immunization coverage for zero-dose children and missed communities,” underscores community[-led] monitoring as a key tool enabling communities to document their health care experiences and inequities faced by populations in vulnerable settings – medication shortages, inaccessible services, and substandard care – and collaborate with health systems to promote reform.<sup>85</sup> A report from the Asia-Pacific Exchange on the Role of CLM in TB Programming emphasized that CLM is a powerful model for sustainably improving access to and quality of TB services.<sup>86</sup>

## Data Action Plan

### Action 14

#### CSOs monitor and address TB vaccine availability, accessibility, affordability, and acceptability.

CSOs possess significant expertise in employing CLM to track and report issues related to treatment access, including medication stock-outs due to inadequate or disrupted supply chains. A recent report by ITPC Global highlighted ten success stories from African community-based organizations in which they deployed an adapted CLM tool with 25 indicators.<sup>87</sup> The work led to substantial improvements in pre-exposure prophylaxis (PrEP) uptake among young women, enrollment in differentiated service delivery models, voluntary medical male circumcision, and a marked drop in TB medicine stock-outs between 2022 and 2023, among other areas.

There are several digital tools with a proven track record for effective monitoring, such as OneImpact, I-Monitor, Pereboi websites, and platforms such as CLM-Asia and Ritshidze. Some tools, such as the CLM-Asia platform, contain a dedicated section on specific vaccines (here, hepatitis B). These questions address issues such as administration of the birth dose, completion of the three-dose schedule, and vaccination costs.<sup>88</sup> The Pereboi websites are a forum for service users to report stock-outs or other challenges around treatment access. These websites have been highly

effective rapid response tools during crises, such as the COVID-19 pandemic and armed conflicts. During crises, PLHIV without access to antiretroviral therapy were able to obtain consultations, referral support, and medicines from emergency donations.

These digital tools facilitate prompt communication with community members at the grassroots level and enable the collection and analysis of data while preserving the anonymity of information providers. With appropriate adaptation, these platforms can easily be expanded to monitor access to TB vaccines. CLM interventions should be implemented at both the national and regional levels, with technical support from global CSOs as appropriate.

#### **Ideal scenario:**

There is a sustainable CLM system related to new TB vaccine rollout with a mechanism for providing feedback and discussing optimization with relevant stakeholders. CLM interventions are implemented at global, regional, and national levels with technical support from global CSOs as appropriate.



## Data Action Plan

“**T**he community plays a key role in collecting vaccine demand data in individual countries and regions, with a focus on actual needs, rather than needs dictated by available funding. This data is essential for further advocacy in vaccine approval, inclusion in treatment protocols, immunization programs, procurement planning, overcoming price and patent barriers.”

### CSOs use CLM tools to track ongoing issues related to TB vaccine access.

CLM tools can be employed to monitor key parameters related to the development, delivery, and demand for new TB vaccines. CLM models and indicators can be tailored to the specific characteristics of each vaccine type and project goal. Potential initiatives may include surveys to understand reasons for vaccine refusal, identify zero-dose priority populations, estimate drop-off rates between doses for multidose vaccines, and uncover unique barriers to vaccination for certain key groups and approaches to mitigate them.

The following list presents areas of focus for CLM accompanied by illustrative examples:

- **Vaccine Trial Status:** TAG publishes regularly updated Pipeline Reports that provide essential information on the progress of TB vaccine research in clear and accessible language.<sup>89</sup>
- **WHO Prequalification Status:** The WHO maintains a list of prequalified vaccines,<sup>90</sup> forming a comprehensive database that CSOs can use to cross-reference national approval data against products with WHO prequalification status.
- **Country Filing and Approval Status:** The Eurasian Community for Access to Treatment routinely monitors the approval status of medicines and diagnostics for HIV, HCV, and TB in countries across Eastern Europe and Central Asia and disseminates this information to relevant stakeholders.
- **Vaccine Procurement, Focusing on Volumes and Price:** The International Treatment Preparedness Coalition (ITPC) monitors procurement activities for drugs treating HIV, HCV, and TB globally. These data are used to inform decision makers about potential challenges and to propose solutions for improving access. Examples include comparative analysis of drug prices

## Data Action Plan

across Latin American countries conducted by RedLam and procurement monitoring in Eastern Europe and Central Asia facilitated by ITPC EECA.

- Shortages and Stock-Outs: Community Treatment Observatories, implemented by ITPC in Africa, and Pereboi websites in Eastern Europe and Central Asia have proven effective in mitigating stock-outs and ensuring consistent supply of essential medicines and vaccines.<sup>91</sup>
- Barriers to Accessing Health Care Institutions: Data from CLM initiatives, such as CLM-Asia and Ritshidze in South Africa,<sup>92</sup> have helped facility managers and health care providers enhance service quality and address barriers to care.

### **CSOs report CLM results to governments and key stakeholders responsible for shaping TB vaccine policies and practices.**

CSOs should use data generated through CLM to promote the delivery of quality services and to adapt existing programs, policies, and strategies. This can only occur if CLM results are shared with and recognized by government partners. Ongoing policy dialogue constitutes a fundamental element of community-led monitoring and research.

CSOs employ a range of advocacy tools to disseminate CLM findings to stakeholders, including stakeholder correspondence, campaigns, and participation in multistakeholder forums. To maximize impact, it is essential that advocacy is a core element of all CLM projects.

“CLM indicators should be aligned with TB vaccine product characteristics and developed by community organizations through collaborative consultations with beneficiaries [...] There should be a set of agreed-upon indicators to enable comparison of results from various CLM projects across the globe.”



## Data Action Plan

### Action 15

**CSOs contribute to vaccine pharmacovigilance systems maintained by governments and industry.**

**G**athering data about adverse events (AEs) associated with vaccine administration is more effective when beneficiaries and health care workers are aware, motivated, and supported to use pharmacovigilance instruments. CSOs can provide information about real-life experiences of vaccine use to government authorities and manufacturers based on community monitoring and feedback.

CSOs are in a unique position to identify side effects and AEs of demand-limiting concern, i.e., concerns at the front of mind for people hesitant to get vaccinated. AEs tracked by routine pharmacovigilance may not always be the same as those side effects that dissuade people from getting vaccinated or become publicly salient drivers of vaccine hesitancy. Similarly, AEs that matter in implementation may differ from those that stand out as significant in clinical trials.

#### **Ideal scenario:**

CSOs strengthen pharmacovigilance of new TB vaccines by ensuring that information about AEs is gathered from vaccine beneficiaries and health care providers and communicated to the relevant authorities and vaccine manufacturers.

**CSOs raise awareness among vaccinated people and health care workers about how AEs can be reported.**

Both governments and pharmaceutical companies use pharmacovigilance systems to assess vaccine safety after approval and introduction. There are typically public websites where health care workers and patients can leave feedback using standardized pharmacovigilance forms. CSOs should include information about these resources and provide training in how to use them through their capacity-building activities and information materials for communities and health care workers.

**CSOs communicate community issues related to pharmacovigilance results to governments and industry.**

Data related to pharmacovigilance gathered through CSO activities should be promptly communicated to government authorities and pharmaceutical companies using existing communication platforms and inform communication strategies of new TB vaccines. CSOs should seek to identify any AEs that appear to soften demand for TB vaccines, contribute to hesitancy, or become the focus of mis-/disinformation.



## Data Action Plan

### Action 16

Funders and vaccine developers involve CSOs in defining a post-marketing research and implementation agenda.

Phase IV post-marketing studies are crucial for generating additional safety and effectiveness data, particularly for special populations and for evaluating potential expansion of product indications. As in the Development stage, CSOs should play a meaningful role in shaping these studies and disseminating results. Drawing on core expertise, CSOs are well positioned to submit proposals for research projects focused on expanding policy indications for new TB vaccines, addressing community needs, and ensuring that priority groups who may not be covered by initial policy recommendations – such as children and pregnant women – are appropriately considered.

**CSOs provide feedback to vaccine developers and funders about the design of and priorities for phase IV trials.**

This can be done using the same mechanisms as described in the Development section, through the involvement of CABs at all levels in advance of the trial design finalization.

**Funders and vaccine developers communicate study results to community groups and other interested stakeholders.**

This can be done using the existing communication and capacity building infrastructure, through briefing webinars, trainings, and information materials (see Development).

#### **Ideal scenario:**

Funders and vaccine developers involve CSOs as key stakeholders in designing a post-marketing research agenda for new TB vaccines, from study development to results dissemination.



## Data Action Plan

### Action 17

#### Funders invest in CLM interventions for TB vaccines.

CLM interventions linked to TB vaccine access should be a priority for funding programs supporting the introduction of new TB vaccines. CSOs are encouraged to develop and propose CLM interventions that are tailored to their national contexts and address the specific needs of key populations. Donors should fund this work as an integral component of delivery and demand creation. Maintaining a focus on monitoring and advocating for equitable access to TB vaccines for priority populations in settings where they are criminalized or highly stigmatized is of particular importance.

There are several areas in CLM that will require investments from stakeholders to optimize access to new TB vaccines, especially for key groups:

- Development of community-led monitoring and research methodology for new TB vaccines
- Adaptation of existing CLM and research tools for new TB vaccines
- Monitoring vaccine access for specific key groups that can be better reached by community organizations: adolescents, people using drugs, migrants, prisoners, PLHIV, etc.
- Expanding existing monitoring tools to other countries/regions (adaptation to national context, translation into local languages)

Monitoring and advocacy projects are less likely to receive government support, as they often expose systemic vulnerabilities and propose reforms that are typically met with some resistance from health care systems in their initial phases. Donors are strongly recommended to designate CLM as a specific funding track in calls for proposals for CSO support. This track should exist alongside those for service delivery, awareness raising, and demand promotion, ensuring comprehensive support for equitable access to TB vaccines.

Donors and governments should establish flexible funding programs to support a variety of CLM interventions. CSOs should be involved in the development of grant programs to ensure funding schemes are well suited to produce locally meaningful results. To achieve sustainability and regularity – key to effective monitoring systems – multiyear grants are preferable.

#### **Ideal scenario:**

Funders incorporate CLM as a priority area for funding calls and support such initiatives worldwide. Governments support CLM related to tuberculosis vaccination by incorporating community data and insights into immunization program planning and review. CSOs develop and submit CLM proposals concerning TB vaccine access at all levels.

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