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Summary report

Towards a proposal for a novel TB vaccine R&D financing initiative

Roundtable discussion on innovative financing for TB
vaccine R&D

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Introduction

This report captures the key insights from a roundtable discussion, convened on 14 October 2024 at the World Health Assembly in Berlin, focused on innovative financing mechanisms to support the late-stage development of tuberculosis (TB) vaccines.

Despite exciting recent progress in developing new TB vaccines, chronic funding scarcity is a major barrier to advancing promising candidates through licensure, particularly as they progress through the complex and costly late-stage clinical development phases. While many governments, philanthropic organisations and others have been generous in supporting TB vaccine R&D to date, it is clear that in the coming years innovative funding strategies and investment models will be needed. In the context of increasing global TB burden, the promise of TB vaccine candidates, and their projected public health and economic benefit, the time is ripe for innovative and coordinated financing solutions to help fill the funding gap.

The WHO TB Vaccine Accelerator Council has brought newfound political momentum to a longstanding challenge, further underscoring the unique opportunity and imperative to identify new funding sources and establish mechanisms that will facilitate late-stage development of new TB vaccines and pave the way to affordable global access of those vaccines.

The roundtable convened 26 experts from diverse sectors, including global health financing institutions, regional development banks, multilateral organizations, academia, industry, philanthropy, and social finance. The session aimed to harness expert perspectives on potential financing strategies and criteria that could be applied to TB vaccine development. The meeting was conducted under Chatham House Rules.

This report is structured around three thematic areas that emerged during the discussion:

1. Enhance the role of high TB burden middle-income countries (MICs) in vaccine financing
2. Diversify the range of funders and aggregate funding for TB vaccine R&D
3. Align the interests of different stakeholders and ensuring robust coordination and leadership

1. Enhance the role of high-burden MICs in TB vaccine financing

Participants agreed that high-burden middle-income countries (MICs) can play a critical role in TB vaccine development and deployment, particularly given the substantial socioeconomic and public health impact new TB vaccines are projected to have in these countries. The active participation of MICs is essential to help expedite the development of new TB vaccines and ensure they are accessible to those who need them the most. Effective engagement of these countries could yield important progress across several key areas:

Investment and resource mobilization: By committing domestic public sector funds/resources and partnering with international organizations and private investors, MICs can support a more sustainable financing model, inspiring greater investments from a diversified body of funders and sharing R&D risks. MICs can also use their own purchasing power and financing capacities to help shape future markets and incentivize late-stage R&D by ensuring the timely implementation of pull mechanisms such as volume guarantee schemes, paving the way to equitable and sustainable access.

Local manufacturing capacity: Many high-burden MICs already possess the infrastructure and expertise necessary for vaccine production. Leveraging this capability can facilitate greater regional ownership of manufacturing, reducing the dependency on external suppliers and enabling faster and

more cost-effective rollout of vaccines once they are developed. The existence of local manufacturing capacity can also help incentivize local R&D investments.

Advocacy and policy influence: Some MICs play an important role in setting the international policy and regulatory agendas for new vaccines. For example, the Ministerial Board of the WHO TB Vaccine Accelerator Council is co-chaired by the ministers of health of Brazil and Indonesia and includes high-level representatives of a number of high TB burden MICs. MICs also have significant influence in global health forums (such as the BRICS and G20). They can also effectively engage with local communities during the R&D process to build trust and address issues such as vaccine hesitancy, which is vital for successful uptake of new TB vaccines.

2. Diversify the range of funders and aggregate funding for TB vaccine R&D

Diversifying the pool of donors and funding mechanisms is crucial to ensure sufficient and sustainable funding for TB vaccine R&D. Collaborative models which aggregate funds across a range of funders can also enable risks and benefits to be shared across funders, making it feasible for more funders to play a role and lowering barriers to accelerated product development. Relevant strategies to diversify the range of funders include:

Leveraging public and philanthropic contributions: To date, TB vaccine development has typically failed to attract sufficient industry or other private investment, meaning R&D has relied mostly on grant funding from public and philanthropic sources. However, this funding pool remains limited. An innovative initiative will require push incentives in the form of additional grants from public and philanthropic funders to de-risk and incentivize investments by a broader group. Complementary pull financing schemes and other measures to align incentives could encourage greater private sector engagement.

Market shaping and pull financing: Innovative and blended financing approaches can attract new public and private sources of funding, linking sufficiently attractive financial returns to the successful achievement of public health outcomes. This can include pull mechanisms, including both financing and procurement options, designed to shape healthcare markets by increasing suppliers' certainties about expected demand, such as Advance Market Commitments (AMCs) and price guarantees. Aggregated, multi-country volume guarantees can also help demonstrate viable markets, supporting price reductions and stimulating economies of scale.

Partnering with development banks: By providing blended financing in the form of grants, loans, and/or guarantees, development banks – such as the European Investment Bank (EIB), the World Bank, and other regional development banks – can help de-risk investments and facilitate late-stage development of TB vaccines. Given the limited ability for developers to recoup expenses while sustaining affordable pricing for LMICs, even in the case of success, funding agencies have an important role in minimizing the burden of loan repayment. Pairing pledges of grant funding with loan mechanisms can be one strategy to de-risk and guarantee loan repayment.

Engaging multilateral organizations: Multilateral organizations (including both intergovernmental bodies such as the G20 and multilateral financing mechanisms such as Gavi and the Global Fund) will be integral to accelerate TB vaccine development and deployment. By providing funding, facilitating collaboration, sending market signals, offering technical assistance, and elevating TB vaccines in global health agendas, these entities can help ensure that efforts to develop and roll out new vaccines are effective and sustainable.

Incorporating private sector investment: The private sector can provide substantial financial resources, particularly if innovative models are introduced that encompass complementary push and

pull mechanisms to help de-risk private sector investments. For example, mechanisms such as impact investing, whereby returns are tied to social outcomes, may attract private investors interested in opportunities that yield both financial and societal benefits.

3. Align the interests of different stakeholders and ensure robust coordination and leadership

With numerous different funding agencies, research institutions and other organisations involved in TB vaccine R&D and introduction planning, robust orchestration is essential to maximize the effectiveness of any novel financing initiative. Effective coordination can minimize duplication and fragmentation across the product development continuum while maximizing funding efficiencies. By working together, stakeholders can leverage their strengths and share risks. Key considerations include:

Coordination and partnership building: TB vaccine development involves a complex landscape of stakeholders, including governments, multilateral organizations, product developers (both non-profits such as PDPs and private companies), academic institutions, civil society, and affected community members. Each group has different priorities, resources, and expertise. Coordinating these diverse interests is essential to ensure that efforts are aligned toward common goals with shared ownership. The WHO TB Vaccine Accelerator Council anticipates playing a central role as a convener of this coalition of the willing, and as a catalyst of increased political attention and commitment, including through the soon to be launched Financing and Access Working Group.

Informing global and local strategies: Meaningful collaboration across the diversity of stakeholders can ensure vaccine R&D aligns with the needs and contexts of high-burden countries by helping to embed the research and implementation of future vaccines in existing national and local paradigms of TB prevention and treatment. The involvement of high-burden countries is essential to ensure equal and affordable access to new vaccines for the people who need them most.

Transparency and accountability: An orchestrated effort can enhance transparency and accountability across stakeholders, ensuring that resources are used effectively and that commitments are met.

Conclusion and Next Steps

The roundtable proved to be an invaluable forum to foster dialogue among a diverse group of experts, each bringing unique perspectives and insights into the challenges of financing TB vaccine R&D. Participants collectively recognized that the world is at an exciting moment with respect to TB vaccine R&D, with multiple candidates now in late-stage development. However, this situation means funding challenges are more acute than ever and that innovative financing solutions will be needed to support TB vaccine R&D in the future. Moving forward, a concerted effort is needed to broaden and deepen this conversation by engaging additional stakeholders and leveraging the insights gained from the roundtable across the priority areas identified.

Concrete actions recommended to advance the late-stage TB vaccine R&D financing agenda include:

- Identifying a coalition of the willing to catalyze a coherent TB vaccine funding agenda to carry vaccines through late-stage development and licensure
- Establishing working groups to identify and advance concrete recommendations and actions around the priority thematic areas identified
- Linking with and leveraging the WHO TB Vaccine Accelerator Council, including through its Financing and Access Working Group, to help coordinate across financing efforts, with a focus on bringing novel vaccines through late-stage development to widespread implementation.