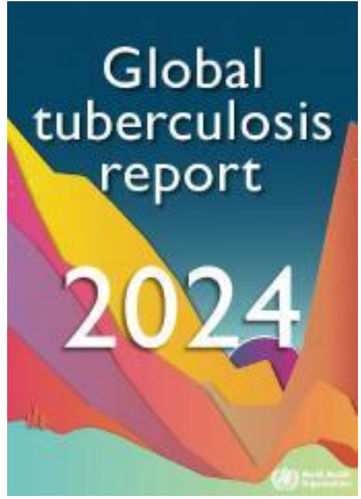
PDVAC session on new tuberculosis vaccines for adults and adolescents

World Health Organization

7 October 2025

The global TB situation

A quarter of the world's population has been infected with TB bacilli.



	Estimated incidence	Estimated deaths
All forms of TB, 2023	10.8 million (10.1–11.7 million) 55% men | 12% <15y	1.09 million* (0.98–1.2 million)
HIV-associated TB, 2023	662,000 (589,000–739,000)	161,000 (132,000–193,000)
MDR/RR-TB, 2023	400,000 (360,000–440,000)	150,000 (94,000–210,000)

* Excluding deaths attributed to HIV/TB

Context

- BCG, the only licensed vaccine, offers protection against severe childhood TB but fails to prevent adult and adolescent pulmonary disease (age groups with highest TB incidence)
- TB vaccines for adults and adolescents are expected to have the greatest impact on disease by impacting transmission and are a public health priority
- Several candidates are in late-stage development and the most advanced could be licensed by 2028.

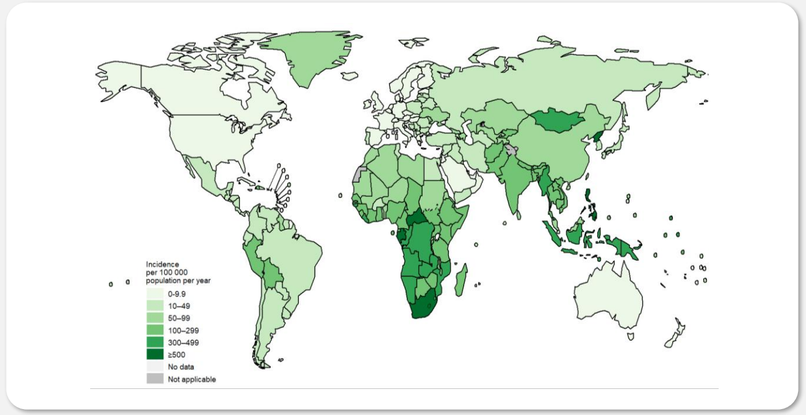
Agenda

09:15-10:15	**New TB vaccines for adults and adolescents**		For information
	•Update on the TB Vaccine Accelerator	Birgitte Giersing (WHO)	
	•Update on the pipeline	Willem Hanekom (PDVAC)	
	•Report back from the TAG for Clinical and Policy Considerations for New Tuberculosis Vaccines, and SAGE	Saskia den Boon (WHO)	
	•Update from the Accelerator Finance & Access WG	Tara Prasad (WHO)	

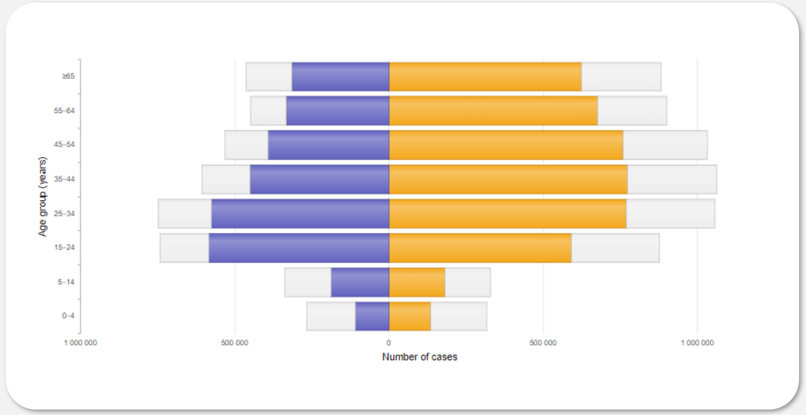
Update on the TB vaccine accelerator

Birgitte Giersing, IVB

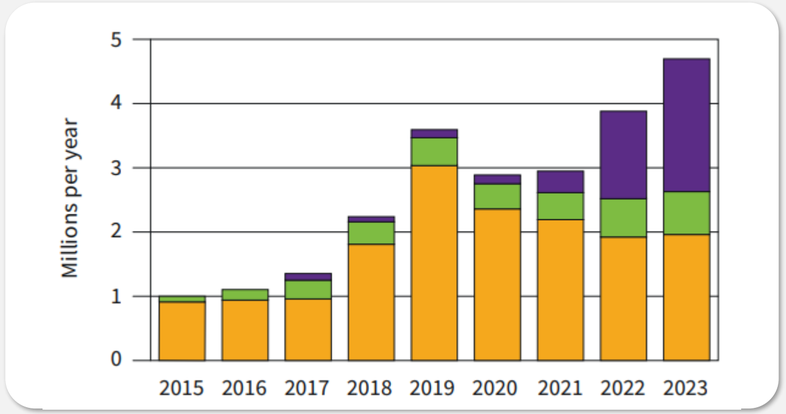
There are many complexities to consider in the introduction of TB vaccines for adults and adolescents



TB impacts low- and middle-income countries. Many are not Gavi-eligible.

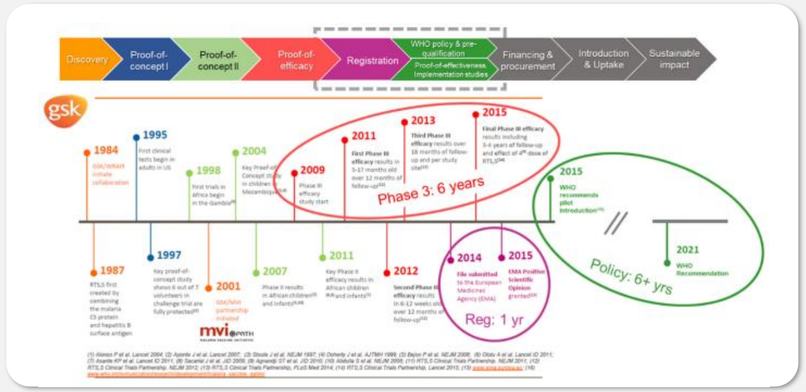


TB incidence and transmission is highest in adolescents and adults. Delivery platform?

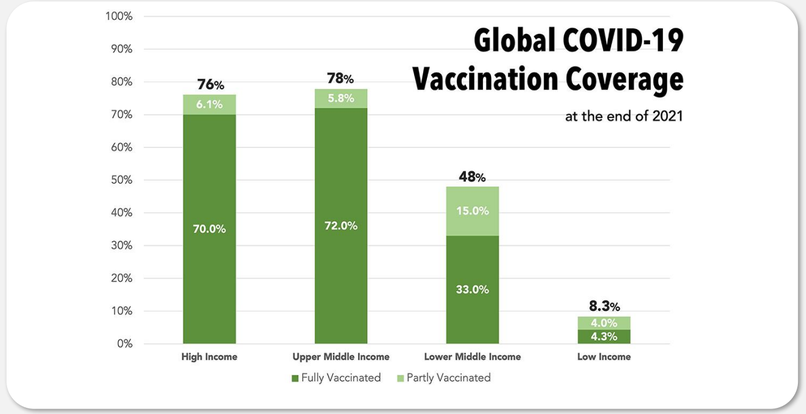


TB preventative treatment (TPT) and other interventions are evolving. How will vaccines fit?

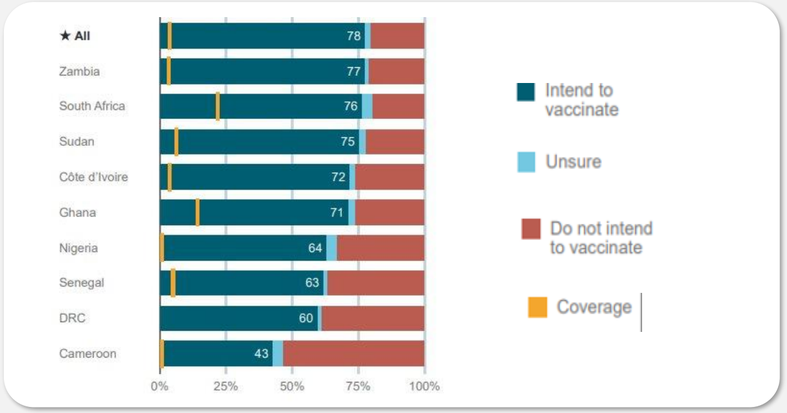
Lessons learned:



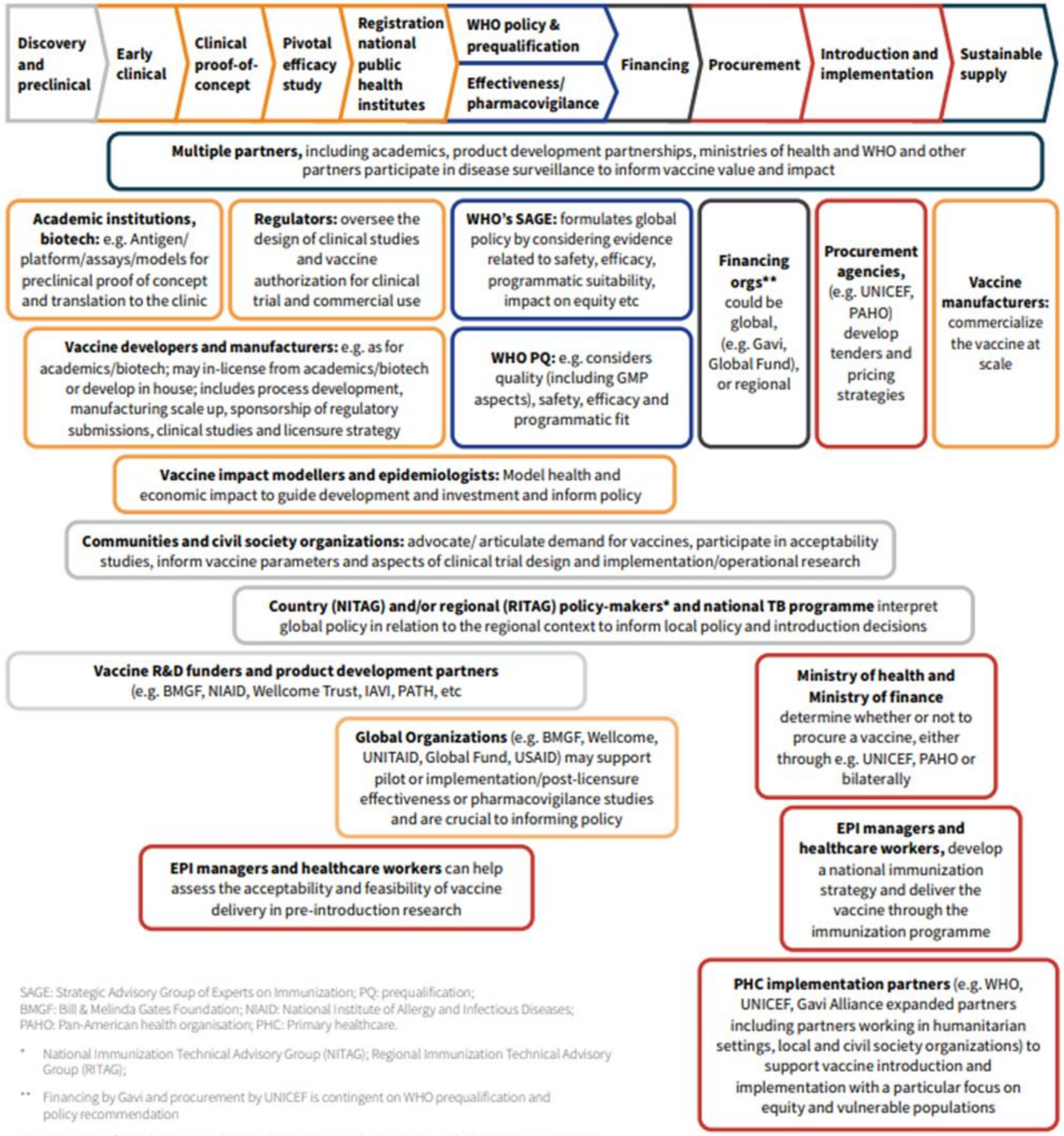
Need to understand the evidence needs for policy to avoid a delay in recommendation.



Need strategies to ensure vaccine is available and provisions in place for equitable access.



Need to build vaccine acceptance through partnership with communities



Stakeholder co-ordination will be key to accelerating vaccine development and implementation

Multiple stakeholders at the country, regional and global level engaged in TB vaccine product development, ensuring supply and equitable access and preparing for uptake

Source:
WHO Evidence Considerations for Vaccine Policy Development for Tuberculosis Vaccines Intended for Adults and Adolescents

In 2023, WHO DG launched the TB Vaccine Accelerator Council

IVB and GTB working together

Members of the Ministerial Board

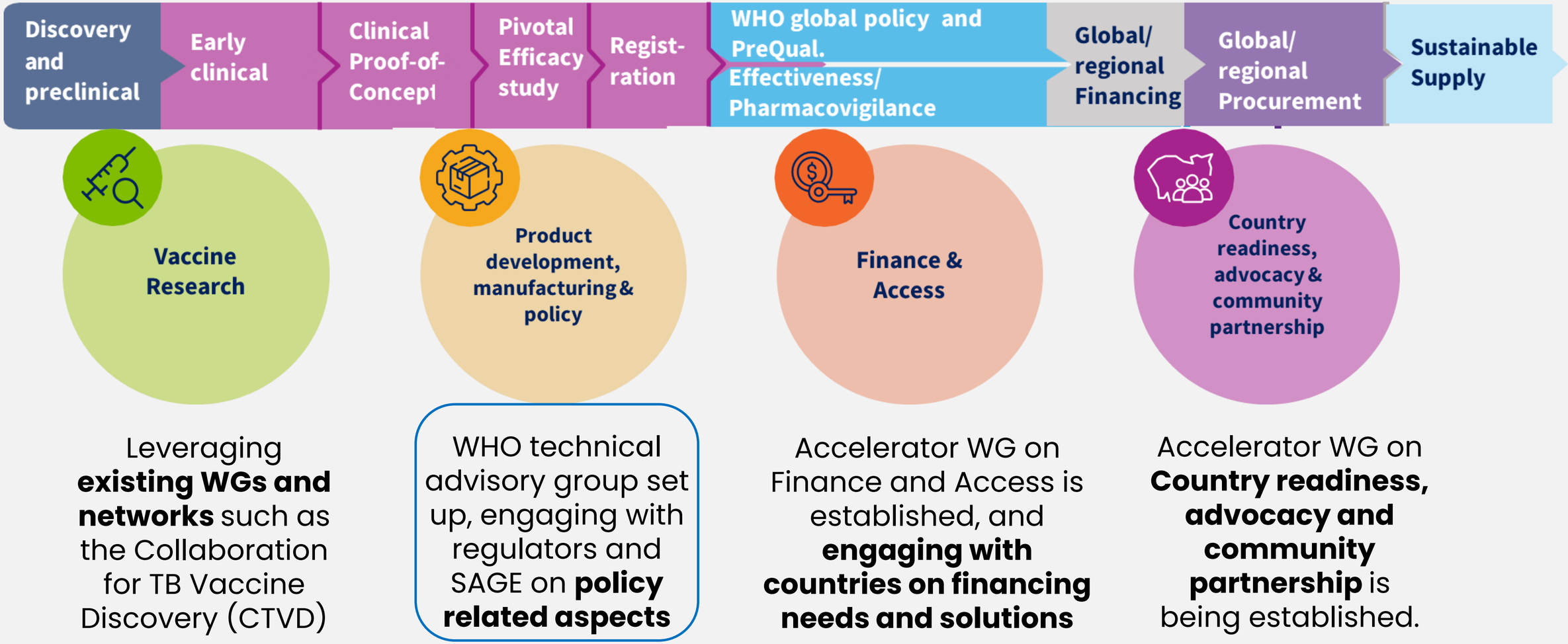
- Minister of Health, Brazil (Co-chair)
- Minister of Health, Indonesia (Co-chair)
- Minister of Social Affairs and Health, France
- Cabinet Secretary for Health, Kenya
- Minister of Health, Viet Nam
- Federal Minister of National Health Services, Regulations and Coordination, Pakistan
- Minister of Health, South Africa
- Secretary of Health, Philippines
- National Institutes of Health, United States of America

Members of the Principal Group

- **Dr Akinwumi Adesina**
  President, African Development Bank Group
- **Dr Trevor Mundel**
  President of Global Health, Bill and Melinda Gates Foundation
- **Ms Nadia Calviño**
  President, European Investment Bank
- **Dr Juan Pablo Uribe**
  Global Director for Health, Nutrition & Population and the Global Financing Facility, World Bank
- **Dr Sania Nishtar**
  Chief Executive Officer, Gavi, the Vaccine Alliance
- **Mr Peter Sands**
  Executive Director, Global Fund
- **Dr Philippe Duneton**
  Executive Director, Unitaid
- **Dr John-Arne Røttingen**
  Chief Executive Officer, Wellcome Trust
- **Dr Lucica Ditiu**
  Executive Director, Stop TB Partnership
- **Mike Frick**
  Co-Director of Tuberculosis Project, Treatment Action Group

- identify needs for, and **types of innovative sustainable market and financial solutions**
- Accelerate TB vaccine development, and **rapidly manufacture and distribute vaccines equitably** and at scale, once they are available
- Develop and **expand access to novel effective TB vaccines, including through political platforms** such as the African Union, ASEAN, BRICS, G20, G7 and others.

Status of setting up technical and strategic working groups of the Accelerator



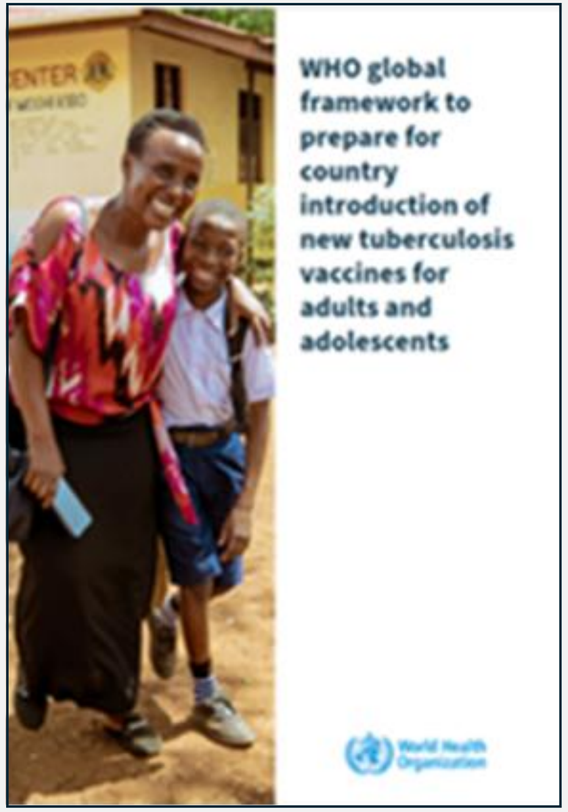
Leveraging **existing WGs and networks** such as the Collaboration for TB Vaccine Discovery (CTVD)

WHO technical advisory group set up, engaging with regulators and SAGE on **policy related aspects**

Accelerator WG on Finance and Access is established, and **engaging with countries on financing needs and solutions**

Accelerator WG on **Country readiness, advocacy and community partnership** is being established.

WHO has developed a Framework that maps out the activities that are needed to prepare for vaccine implementation



https://www.who.int/publications/i/item/9789240086593

Country level

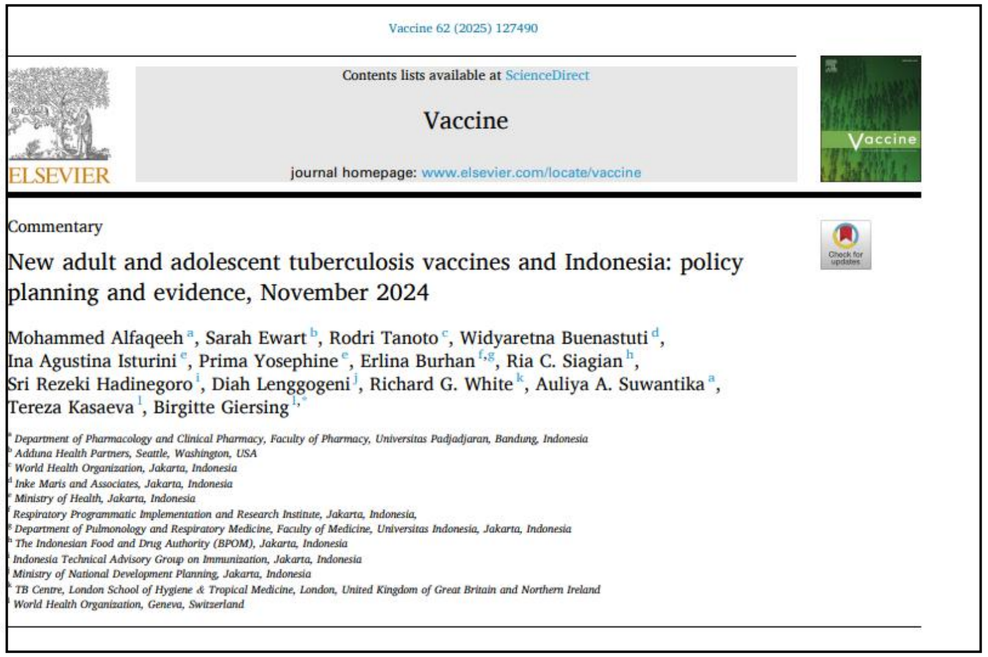
Regional level

Global level

Vision & Purpose	**A world free of TB, with zero deaths, disease, and suffering due to TB**		
	Facilitate rapid introduction and coverage scale-up of new adult and adolescent TB vaccines		
Goals	**Available** Sufficient, sustainable, and timely supply	**Accessible** Equitable delivery aimed at all who could benefit	**Accepted** Policymakers, end-users and health systems requirements met
Milestones	• **Demand assessed** (e.g., no. of doses in short, medium and long term for priority populations; in context of other interventions; with country stakeholders engaged) • **Policy, evidence needs, and pathways defined** (e.g., safety and vaccine efficacy; regulatory approvals; specific populations; in-country trials; recommendations for use; import licensing) • **Procurement plans in place** (e.g., agreements with local, regional and global manufacturers, including on price, quantity and timing)	• **Implementation strategy defined** (for priority populations; vis-á-vis interaction between primary health care, TB, HIV, school health, EPI programs; with private providers and communities) • **Delivery systems in place** (capacity; infrastructure; supply chains; adequate numbers of trained health and community workers; data monitoring; pharmacovigilance; phase IV studies) • **Sustainable financing strategy in place** (e.g., national health sector strategy, external donors, private payers)	• **Value defined** (i.e., at individual and population levels and from perspective of health workers, policymakers, vaccinees) • **Communities engaged as partners in decision-making** (i.e., priority populations, TB survivors, health workers, community health workers, advocates, policymakers) • **Robust communications strategy in place** (e.g., localized; responsive to community concerns and priorities)
Approach	**Accelerated, Coordinated, Integrated, People-centred, Equity-driven, Evidence-based**		
Enablers	**Programmatic suitability**	**Regulatory and Policy**	**Supply and manufacturing**	**Financing and political engagement**
	• Appropriate presentations • Funded implementation research	• Appropriately designed phase III efficacy trials • Rapid, harmonized regulatory pathways to approval • WHO guidance/ recommendation on vaccine use, aligned with broader TB control efforts • WHO prequalification	• Affordable vaccines • Sufficient supply • Sufficient and diversified manufacturing capacity • Access, IP and procurement agreements	• High level political will (G20/G7) • Adequate financing • Clarity on roles of funding partners (e.g., Gavi, the Global Fund) and procurement partners (e.g., PAHO, UNICEF)

Policy to Evidence convening, Indonesia, November 2024:

New adult and adolescent tuberculosis vaccines and Indonesia: policy planning and evidence



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Commentary

New adult and adolescent tuberculosis vaccines and Indonesia: policy planning and evidence, November 2024

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[l] World Health Organization, Geneva, Switzerland

Recommendations by Availability, Accessibility and Acceptability

IVB

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

World Health Organization Indonesia

[New adult and adolescent tuberculosis vaccines and Indonesia: policy planning and evidence, November 2024 - ScienceDirect]

Indonesian policymakers and stakeholders:

- Ministry of Health
- Indonesian TB Expert Committee
- Bappenas Ministry of Planning
- National Agency for Research and Innovation (BRIN)
- National Food and Drug Agency (BPOM)
- Indonesian Immunization Technical Advisory Group (ITAGI)

Global observers: Gates MRI, Wellcome Trust, UNICEF, World Bank, USAID, US CDC, IAVI, CHAI, TAG

Policy to Evidence convening, South Africa, July 2025:

Advancing Policy and Decision-Making for TB Vaccine Introduction in South Africa: A Preparedness Workshop

- High risk groups and implementation strategies discussed
- Evidence gaps and implementation research needs identified
- Political commitment reaffirmed!
- Meeting report in progress
- Roadmap for **Accelerated Implementation of Novel TB Vaccines for Adults and Adolescents in South Africa** – SA MoH and WHO joint publication

Vision: Initiation of nationwide implementation of TB vaccines for adults and adolescents within one-year of regulatory approval.			
Purpose: delineate the milestones, critical activities and key stakeholders to enable rapid national introduction decision-making and equitable coverage scale up of new TB vaccines for adults and adolescents			
Goals	***Available*** *Sufficient, sustainable and timely supply*	***Accessible*** *Equitable, affordable delivery to all who could benefit*	***Acceptable*** *Aligned with expectations of end-users and recipients*
Milestones	Evidence needs and pathways for accelerated policy-setting defined	Implementation strategy defined, based on use cases (i.e., who will get the vaccine and where/how)	Public health and socio-economic value defined in the context of TPT, etc.
	Demand quantified to inform national supply needs	Health systems prepared to support implementation strategy	Community leaders partnering in vaccine implementation
	Investment in local manufacturing capability and capacity for sustainable supply	Financing commitments and procurement mechanisms in place to ensure supply meets demand	Effective communication strategy established

IVB

health
Department:
Health
REPUBLIC OF SOUTH AFRI

World Health Organization
South Africa

Proposed concept for Accelerator Working Group 4 on Country Readiness, Advocacy, and Community Partnership

DRAFT will undergo consultation

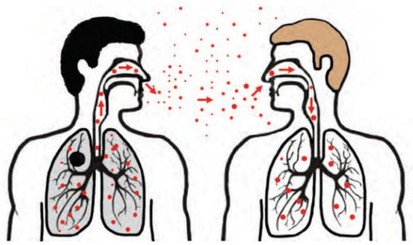
Envisaged as a Community of Practice

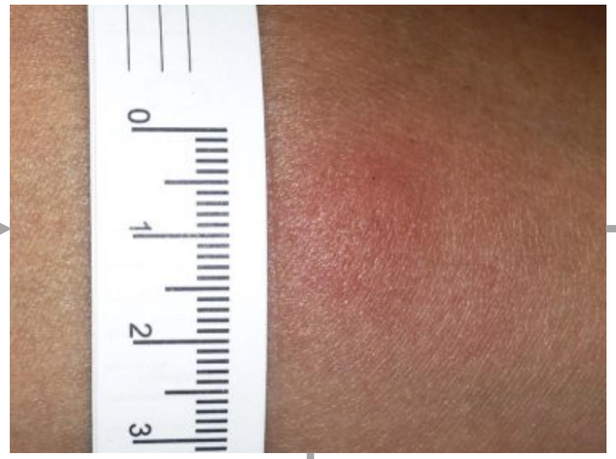
Vision: *to maximize the public health and socio-economic impact of novel, effective TB vaccines through* ***facilitated collaboration within and between countries****, to inform decision making for accelerated and equitable vaccine uptake.*

Update on the TB vaccine pipeline

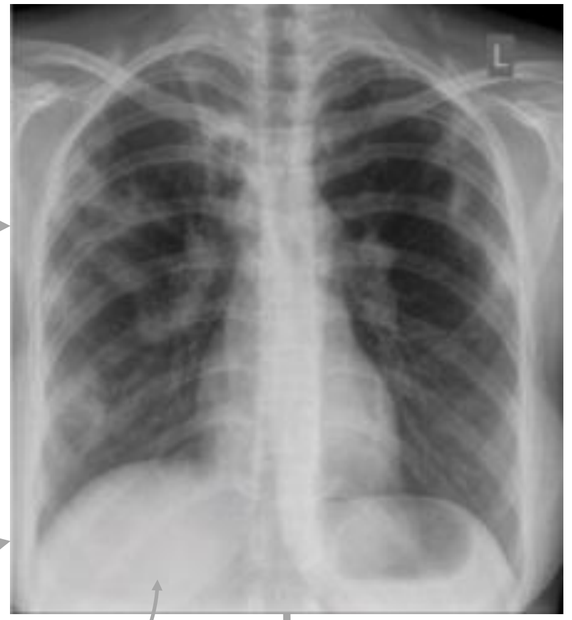
Willem Hanekom, AHRI

How TB vaccines may work.





5-10%



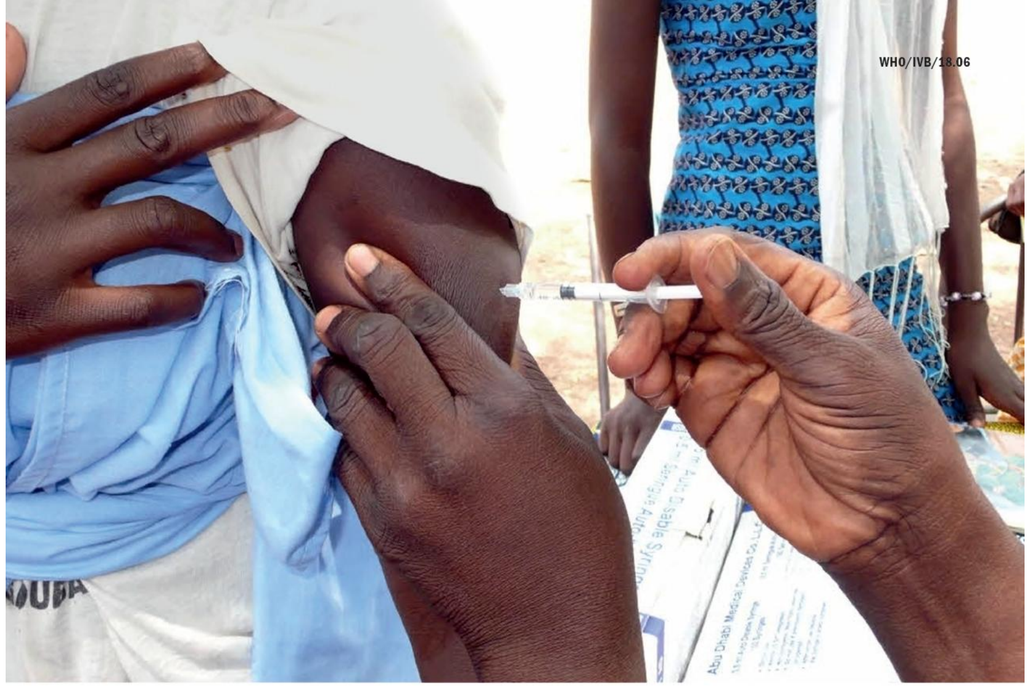
Subclinical TB

Self-cure

~5%

Cure after Rx

Sequelae



WHO Preferred Product Characteristics for New Tuberculosis Vaccines

DEPARTMENT OF IMMUNIZATION, VACCINES AND BIOLOGICALS
Family, Womens's and Children's Health (FWC)
World Health Organization

Infants and children

Adolescents and adults

Even 20% efficacy against adolescent and adult disease would have an impact.

Global clinical TB vaccine development pipeline: prophylaxis in adolescents and adults.

Phase 1	Phase 2A	Phase 2B	Phase 3
AdHuAg85A McMaster Univ, Cansino	**AEC/BC02** Anhui Zifei Longcom	**MTBVAC** Biofabri, Univ Zaragosa, IAVI	**BCG as travel vaccine** HJF
H107e/CAF10b SSI	**BNT164a1 and BNT164b1** Biontech, Gates Foundation		**GamTBvac** Gamaleya, MoH Russia
TB/FLU-05E Smorodintsev/MOH Russia	**ID93/GLA-SE (QTP101)** Quratis, NIH		**Immuvac (MIP)** ICMR, Cadila
			VPM1002 SII, VPM
			M72/AS01$_{E\text{-}4}$ Gates MRI, GSK

Modified from Stop TB Partnership.

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			VPM1002 SII, VPM
			M72/AS01$_{E-4}$ Gates MRI, GSK

1. Whole cell
2. Adjuvanted subunit
3. Viral vectored
4. mRNA

Modified from Stop TB Partnership.

Global clinical TB vaccine development pipeline: prophylaxis in adolescents and adults.

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			VPM1002 SII, VPM
			M72/AS01$_{E-4}$ Gates MRI, GSK

1. Most advanced and promising
2. Fast follower
3. Next generation
4. Where are the results?

Modified from Stop TB Partnership.

Global clinical TB vaccine development: notable recent negative results.

POI

- Revaccinating adolescents with **BCG** does not prevent sustained IGRA conversion.

POR

- Vaccinating patients “cured” with antimycobacterials with **H56/IC31** does not prevent recurrent disease.

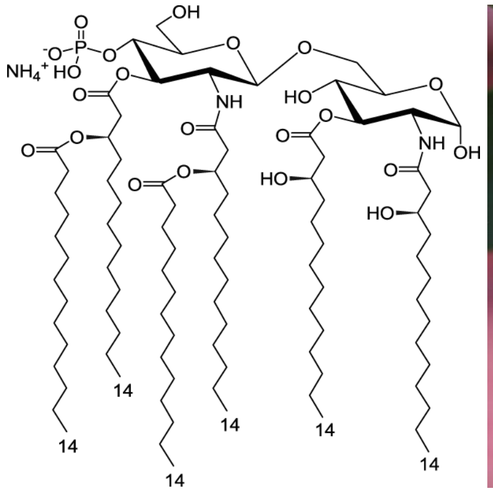
POR

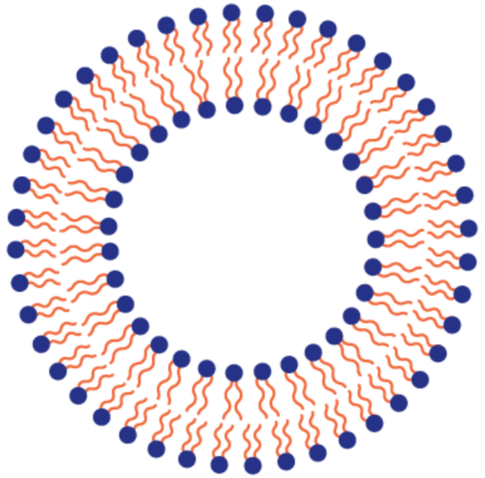
- Revaccinating adults “cured” with antimycobacterials with **VPM1002** does not prevent recurrent disease *(unpublished)*.

1. Most advanced and promising: M72/AS01$_{E-4}$.

1. Fusion peptides of Mtb

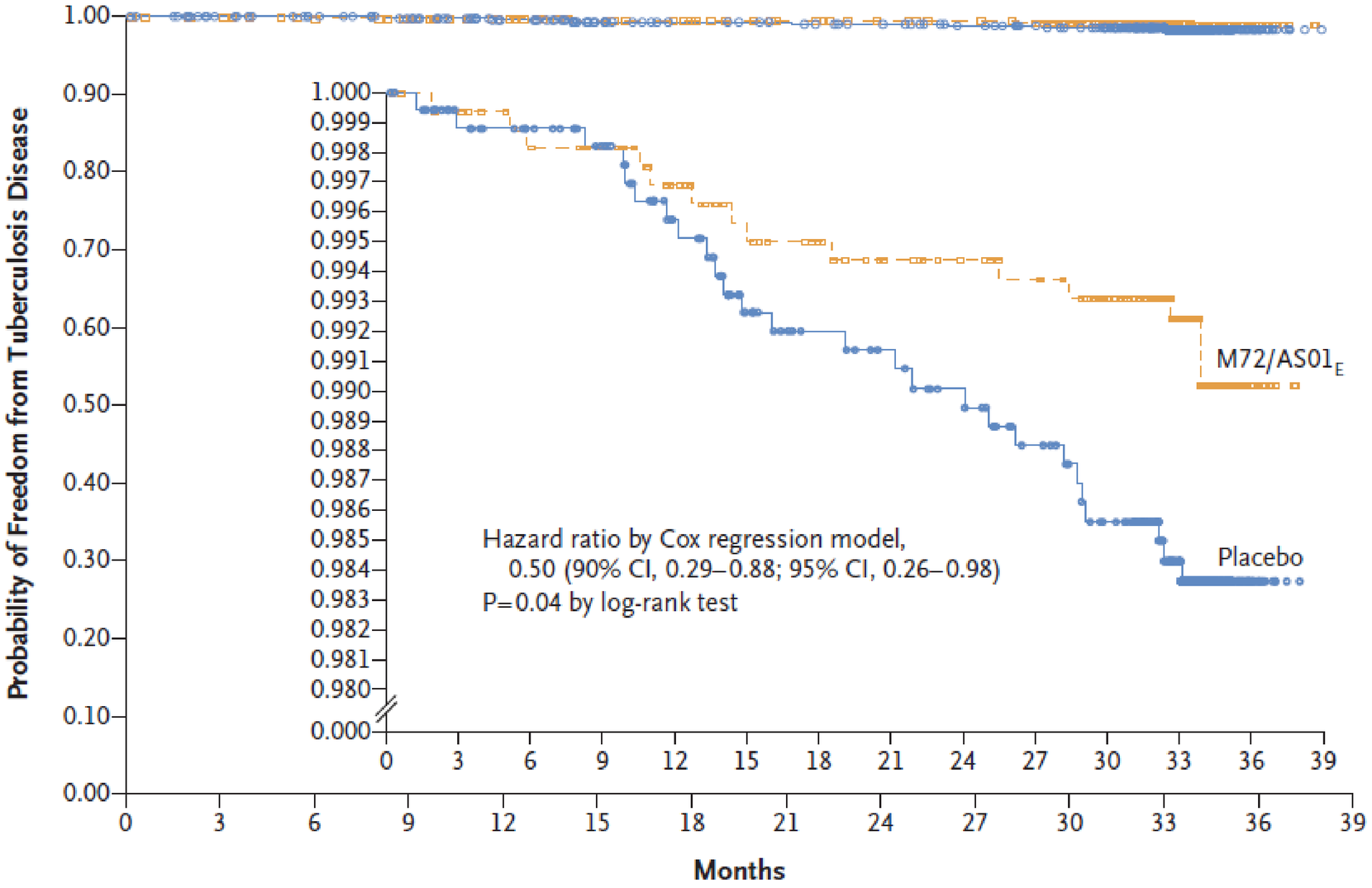
2. AS01E adjuvant: MPL, QS-21, in liposomes





The vaccine is in a phase 3 trial in Africa and Southeast Asia.

Phase 2b: M72/AS01$_{E-4}$ protects against TB disease in QFT+ adults.



Tait, et al. N Engl J Med 2019: *n=3,575*.

M72/AS01$_{E-4}$ phase 3 trial.

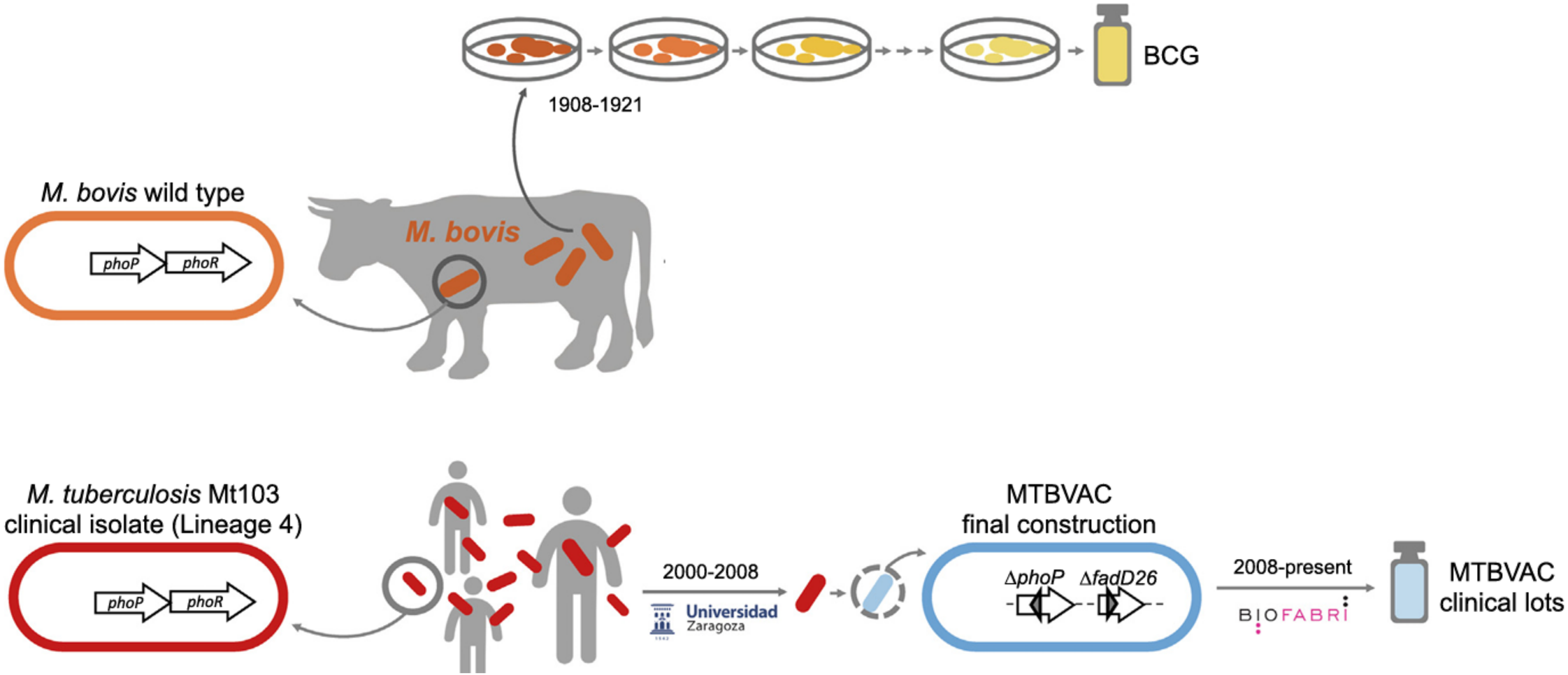
1. **Indication: prevention of active pulmonary TB disease in adolescents and adults, 15 years of age and older.**
   - n=18,000 IGRA+, randomized 1:1 to receive 2 doses of M72 or placebo.
   - VE 55%, lower limit of 95% CI 10%, power>90% requires 110 TB disease outcomes.
   - South Africa, Kenya, Zambia, Malawi, Indonesia, Vietnam.
2. **Assessment of safety and immunogenicity in IGRA negative and PLWH.**
   - n=1,000 each, randomized 1:1 to receive 2 doses of M72 or placebo.

As of April 2025: fully randomised.

Results likely by 2028.

Gates Medical Research Institute.

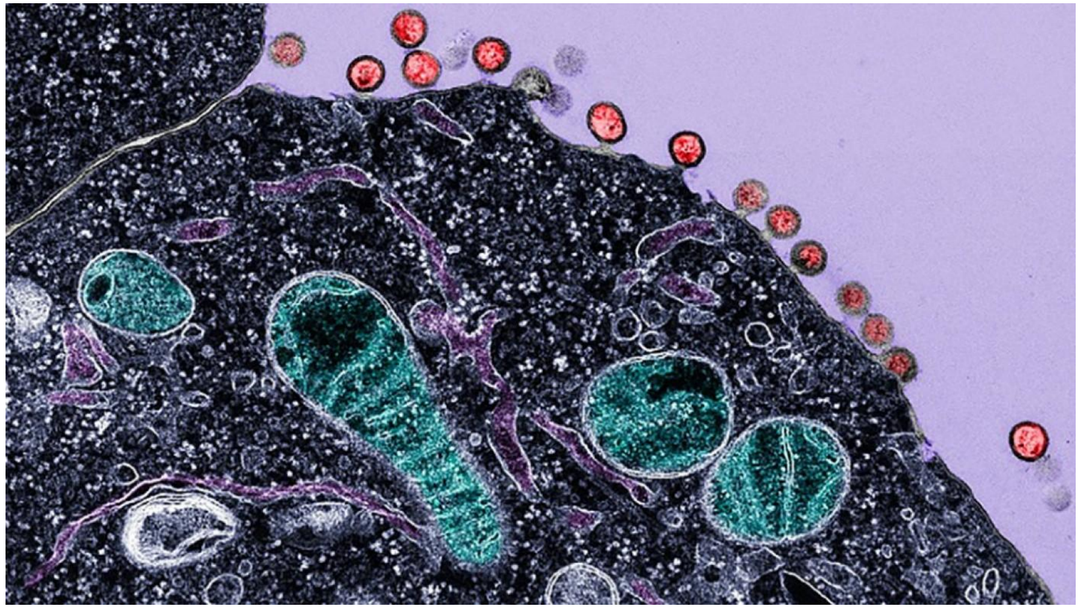
2. Fast follower: MTBVAC.

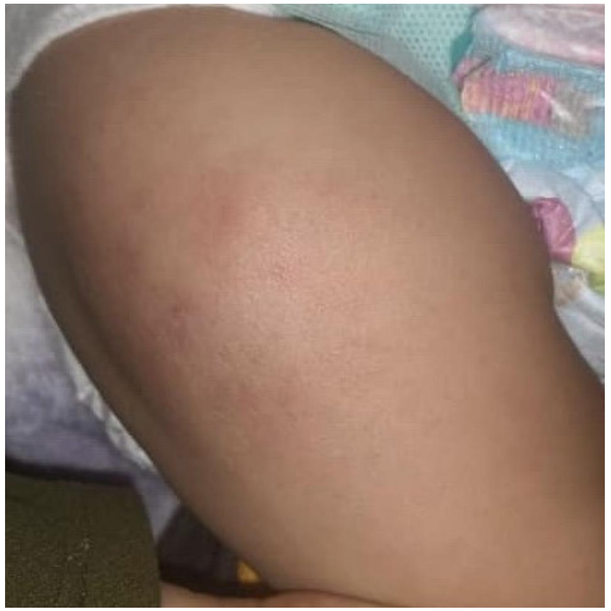


The vaccine is in a phase 2b trial in Africa and a phase 3 trial is planned for India.

Carlos Martin and colleagues.

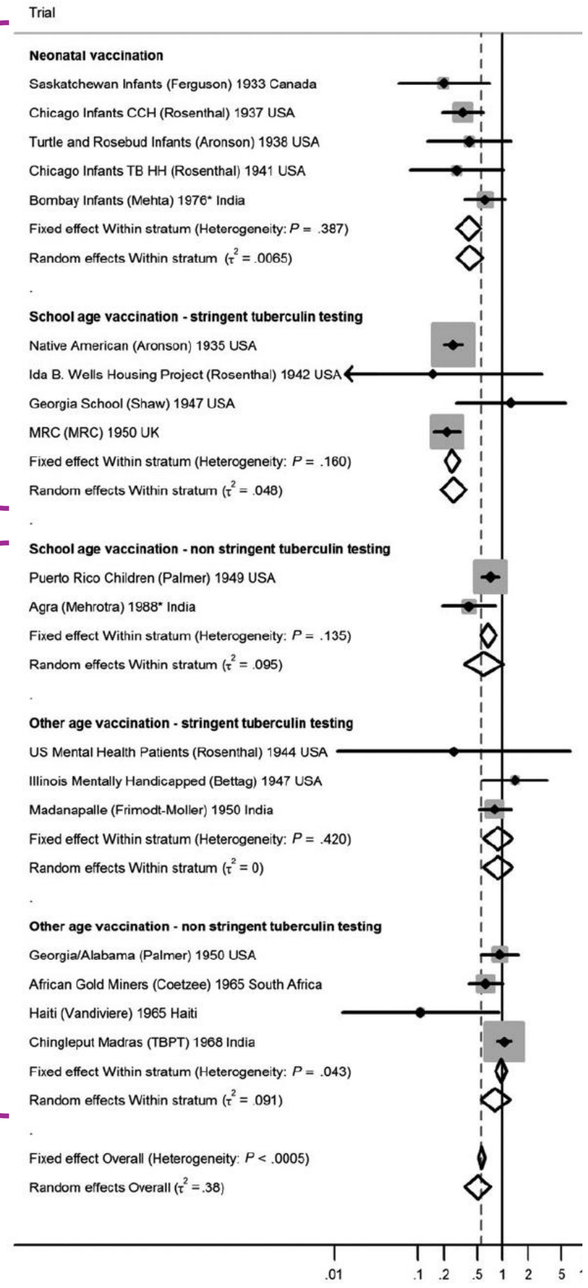
MTBVAC: potential concerns.





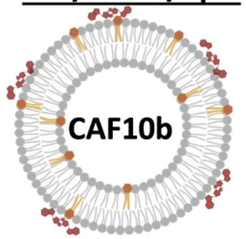
Neonatal and tuberculin skin test (TST) negative

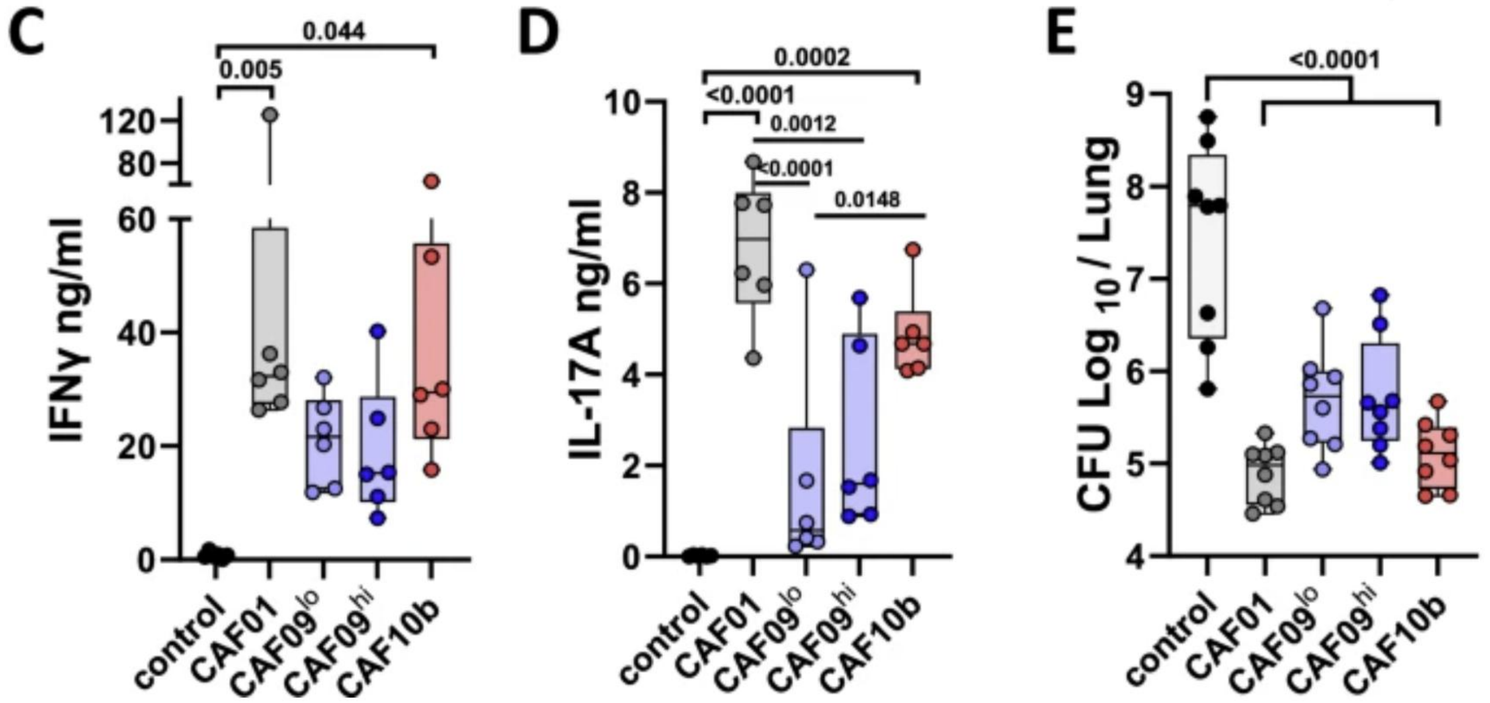
No TST or older



3. Next generation: H107e/CAF10b.

DDA/MMG/CpG

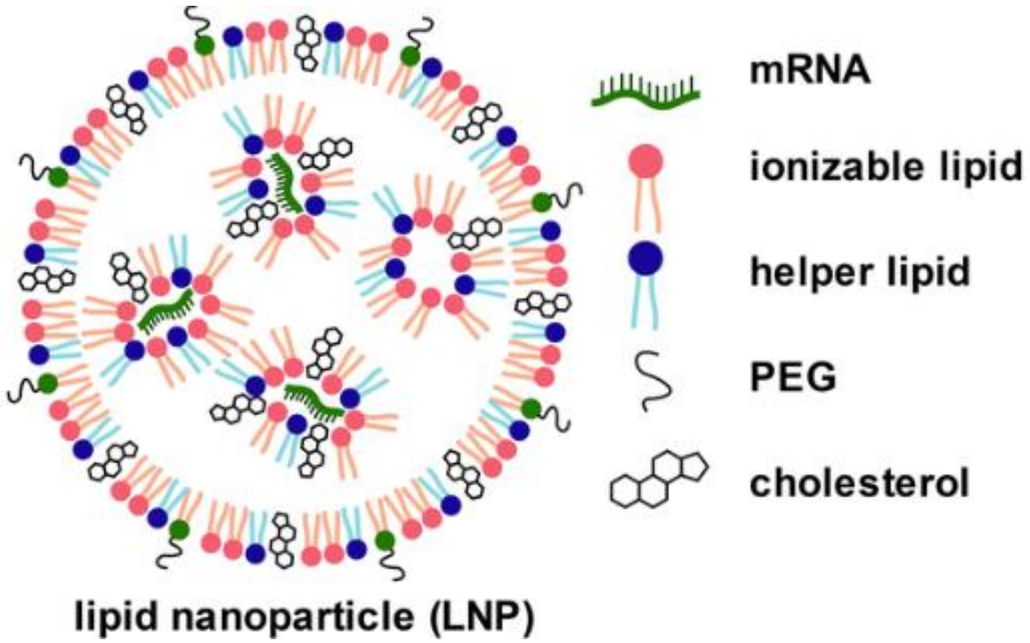




The vaccine is in a first-in-humans trial in South Africa.

Woodworth, et al. Nat Comms 2024;15:8959.

3. Next generation: BNT164a1 and BNT164b1.

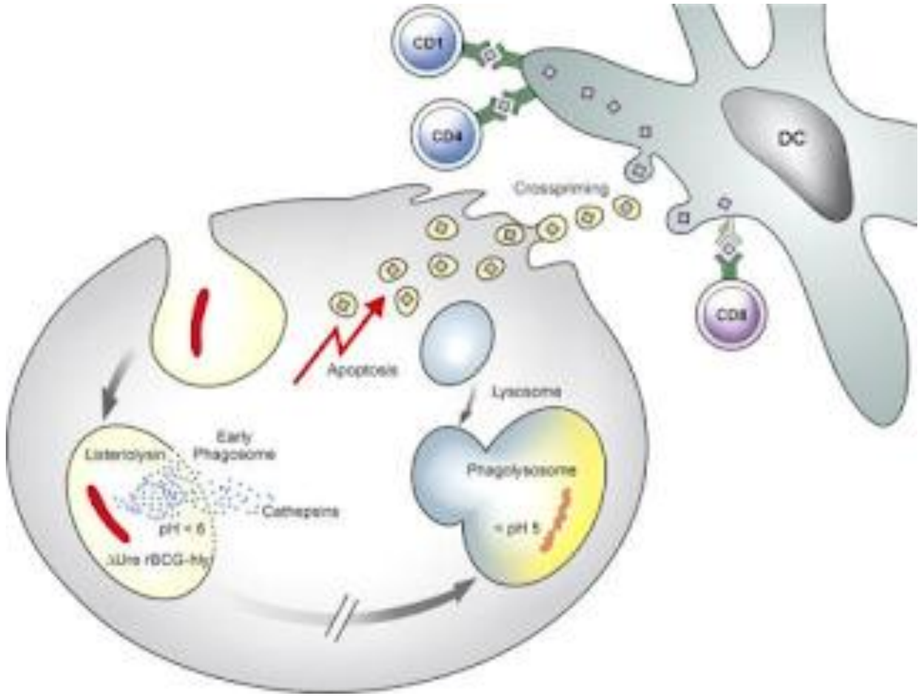


Antigen class: associated with…	Specific proteins encoded
"Latency"	VapB47 Hrp1
Reactivation	RpfA RpfD
Clinical disease	ESAT-6 Ag85A HbhA MTB32A & MTB39A (M72)

The vaccine is in a phase 2a trial in Southern Africa.

Wolf et al. React Chem Eng 2024.
BioNTech.

4. Where are the results? **VPM1002**, or BCGΔ*ureC*::*hly*.



Completed, unpublished efficacy trials:

1. **Prevention of recurrence**

n=2,000. VPM1002 or placebo once 2 weeks after completion of TB Rx.

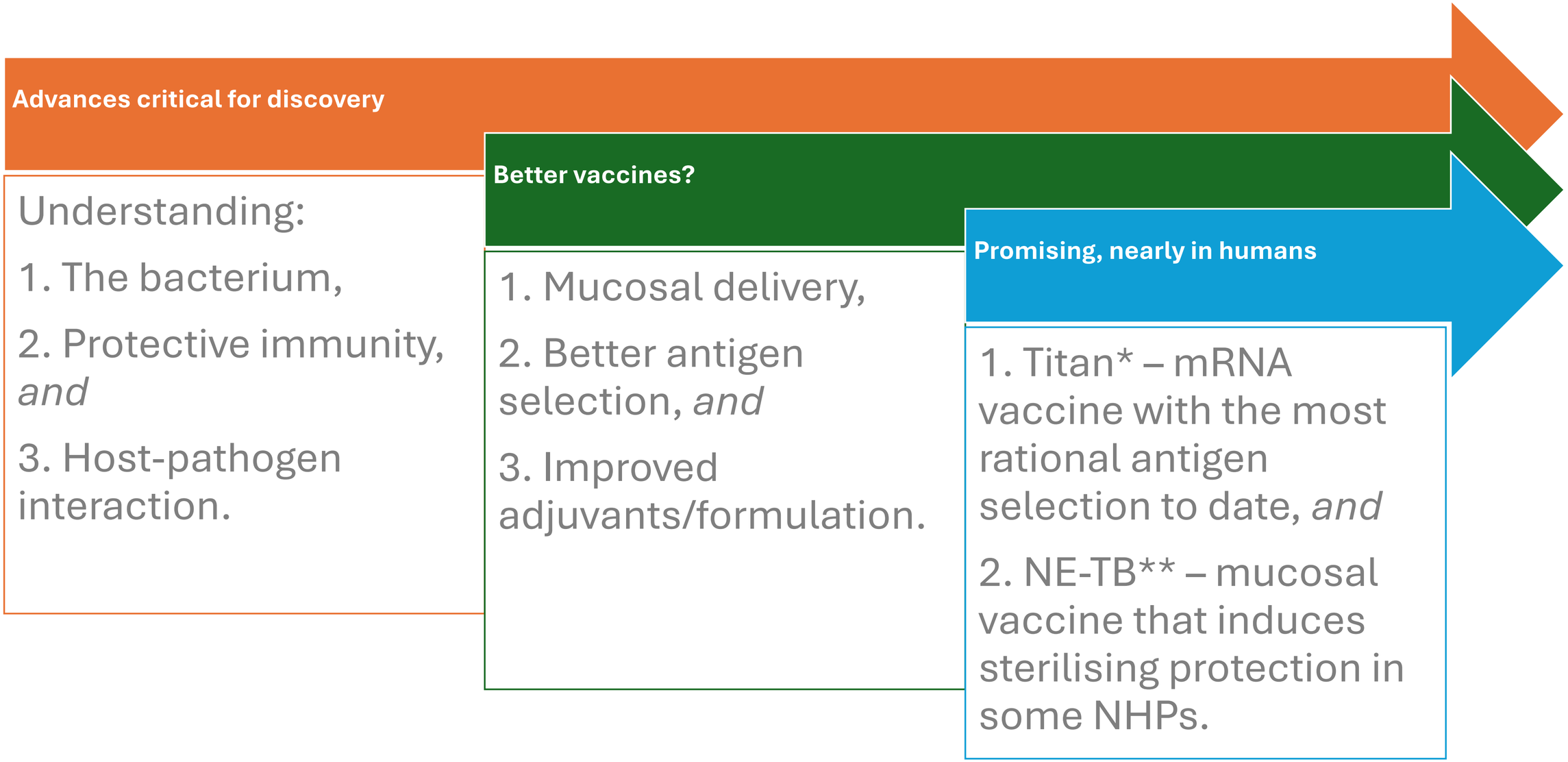
***Presented at TBVI meeting in January 2025:* VE 25.4%, 95%CI -36.7 to 59.4.**

2. **Prevention of disease**

n=13,000 household contacts of persons with TB disease. Two doses of VPM1002 or Immuvac or placebo 1 month apart. Followed for 36 months.

Serum Institute India.

The discovery and preclinical space is dynamic.



*South African Tuberculosis Vaccine Initiative.

**NE: oil in water nano-emulsion. Shabaana Khader, Univ. Chicago.

Report back from the TAG for Clinical and Policy Considerations for New Tuberculosis Vaccines and SAGE

Saskia den Boon

World Health Organization

23 September 2025

PDVAC TB session, Dec 2024 (1)

PDVAC Recommendations:

PDVAC endorses the proposal to establish a TAG on clinical and policy considerations for new TB vaccines, to accelerate the testing, approval and recommendation of late-stage candidates, but also cautions the need for continued investment in the early pipeline to mitigate attrition/vaccine failure.

- This session: report back on the new TAG and activities 2025

Can PDVAC opine on the pathway to evaluate the feasibility of including asymptomatic TB as an endpoint in future pivotal efficacy trials?

- PDVAC supports the proposal for TB TAG engagement with regulators, from both maturity level 3/4 and LMICs, to evaluate the existing data on asymptomatic TB and opine on the data that is needed to assess its feasibility as an endpoint.
- As a second step, if regulatory feasibility can be established, discuss with policy makers in addition to NRAs, in high burden early adopter countries.
- In general, PDVAC supports the collection of sputum at the end of ongoing studies to diagnose aTB and generate data on the number of asymptomatic cases that did not progress to symptomatic TB.

- This session: report back on activities of a TAG subgroup on aTB: rapid evidence review, initial engagement with regulators, planned 2026 activities including consultations with policy makers

PDVAC TB session, Dec 2024 (2)

Does PDVAC still consider there to be value in developing a 'policy position statement' on the preference for a PoD endpoint? If yes, how should asymptomatic TB be included?

The proposal for a position paper on WHO's preference for PoD studies was derived from the 2023 meeting, however several trials with PoI or PoR endpoints have since failed. The vaccine pipeline is almost exclusively focused on prevention of disease endpoints, negating the need for a position statement. However, the role of aTB within the PoD endpoint will be important to assess and is being planned as part of the TAG activities.

What role could the TB Vaccine Accelerator and it's working groups have on facilitating/informing the vaccine manufacturing / commercialization strategy for new TB vaccines?

Though not presented during the open session due to time constraints, the role of the Accelerator was discussed in the closed meeting. PDVAC concurred that the remit of the TB Vaccine Accelerator should include manufacturing, specifically the assessment of data/information that could incentivize investment and integration of manufacturing technology transfer, scale up, production and commercial partnership as part of the critical path to vaccine approval.

- Manufacturing including technology transfer was addressed during TAG discussions with developers

WHO Technical Advisory Group on Evidence for Clinical and Policy Considerations for New Tuberculosis Vaccines

Activities 2025

WHO Technical Advisory Group on Evidence for Clinical and Policy Considerations for New Tuberculosis Vaccines

Gavin Churchyard
CEO, The Aurum Institute, South Africa

Sonali Kochhar
Professor, University of Washington, USA

Marco Cavaleri
Head of Department, Public Health Threats, European Medicines Agency, The Netherlands

Fernanda Dockhorn Costa Johansen
Coordinator, National Tuberculosis Programme, Brazil

Lee Fairlie
Associate Professor, University of Witwatersrand, South Africa

Akbar Fotouhi
Professor, Tehran University, Iran
NITAG Iran

Rakhal Gaitonde
Professor, Sree Chitra Tirunal Institute of Medical Sciences and Technology, India

Joey Gouws
Formerly at Prequalification Unit, WHO, South Africa

Willem Hanekom
Executive director, Africa Health Research Institute (AHRI), South Africa

Rumina Hassan
Professor, Aga Khan University, Pakistan

Mark Hatherill
Director, South African Tuberculosis Vaccine Initiative (SATVI), South Africa

Philip Hill
Professor, University of Otago, New Zealand

Bruce Kirenga
Director, Makerere Lung Institute, Uganda

Tonia Marquardt
Senior Medical Officer, National Centre for Immunisation Research and Surveillance, Australia

Monde Muyoyeta
Director TB Programs, Clinical Trials Unit Lead, Centre for Infectious Diseases Research (CIDRZ), Zambia

Kristin Nelson
Assistant Professor, Emory University, USA

Morten Ruhwald
chief Medical Officer, Novo Nordisk Initiative for Vaccines and Immunity, Denmark

Anissa Sidibe
Principal Technical Advisor for Immunization, Jhpiego, Mali

Jane Soepardi
Formerly Director of Immunization, Surveillance and Health Quarantine, Ministry of Health, Indonesia

Giovanni Sotgiu
Professor, University of Sassari, Italy

Bach Tran
Professor, Vietnam National University, Vietnam

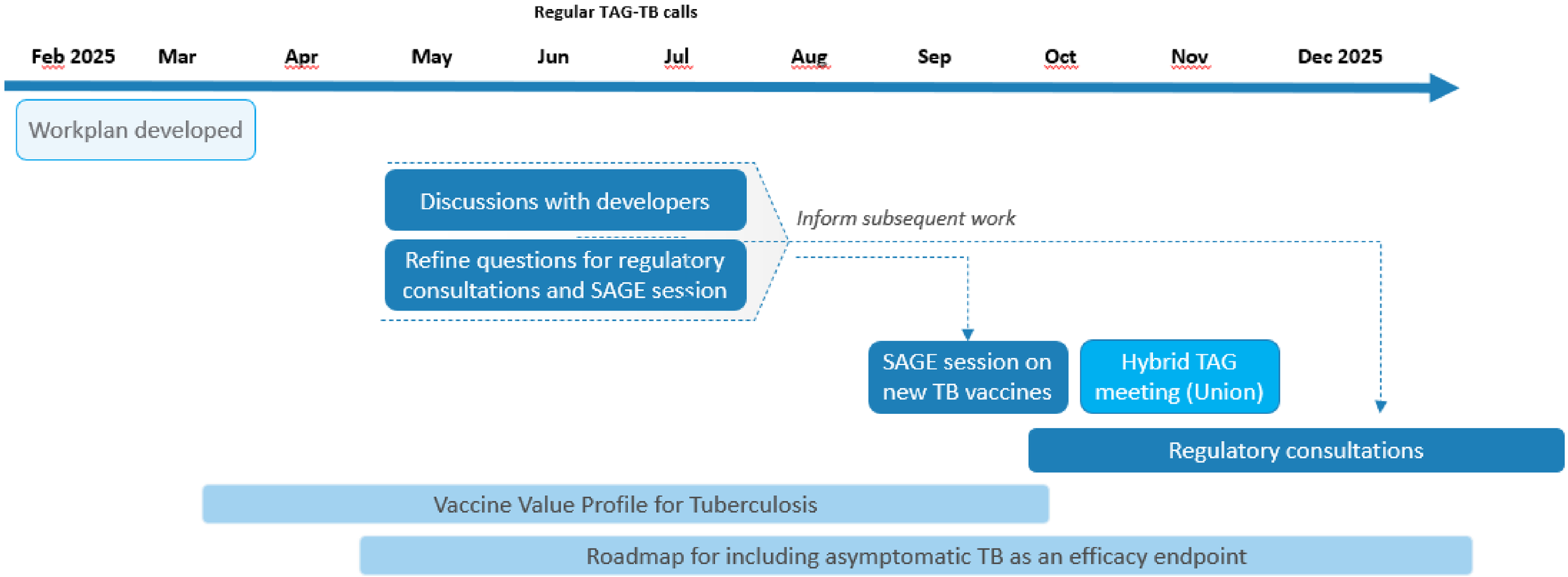
Richard White
Professor, London School of Hygiene and Tropical Medicine, UK

Tony Yang
Professor, George Washington University, USA

- Established January 2025
- Remit:
  - research & development
  - policy preparation

TAG activities 2025

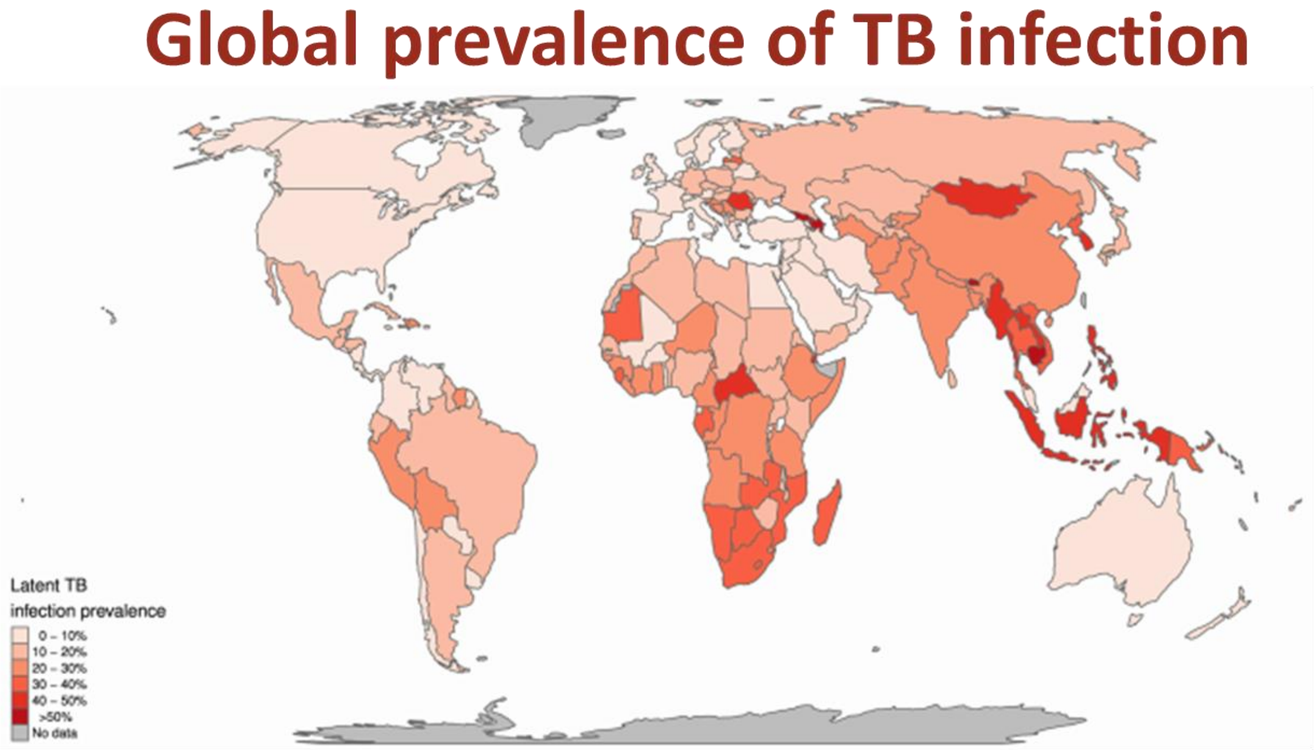
- Bilateral consultations with TB vaccine developers, focusing on most advanced candidates
- Initiation of conversation with regulators (high TB-burden countries in Africa)
- Subgroup on asymptomatic tuberculosis



Key findings from the consultations with developers & highlights from the SAGE meeting

TB epidemiology & implications for TB vaccine trials

- Approximately 25% global population has been infected with MTB
- TB disease develops slowly
  - Among people living without HIV, the life time risk of progressing to disease is 5-10%
  - The highest risk of progressing to TB disease is in the first 2 years post infection



(Houben. Plos Med, 2016)

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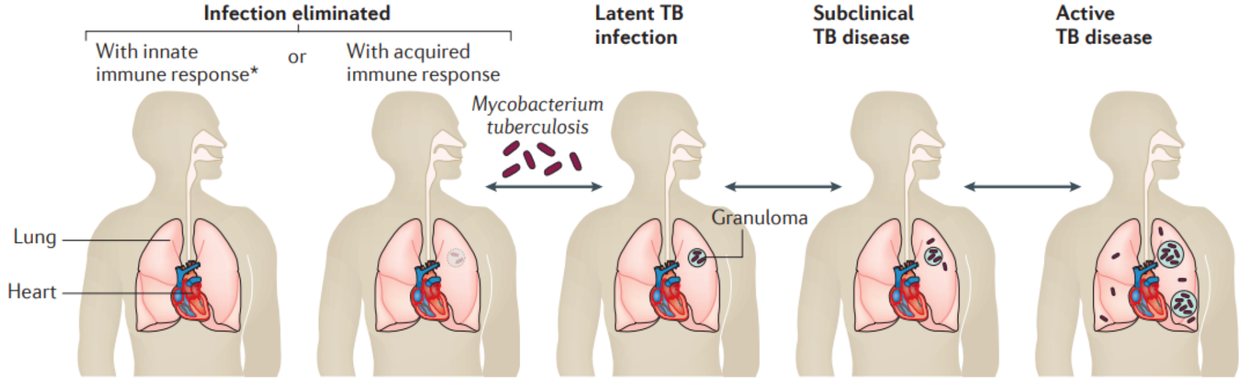

TST	Negative	Positive	Positive	Positive	Usually positive
IGRA	Negative	Positive	Positive	Positive	Usually positive
Culture	Negative	Negative	Negative	Intermittently positive	Positive
Sputum smear	Negative	Negative	Negative	Usually negative	Positive or negative
Infectious	No	No	No	Sporadically	Yes
Symptoms	None	None	None	Mild or none	Mild to severe
Preferred treatment	None	None	Preventive therapy	Multidrug therapy	Multidrug therapy

Pai *et al*. Nature reviews 2016; 2. doi: 10.1038/nrdp.2016.76

TB epidemiology & implications for TB vaccine trials

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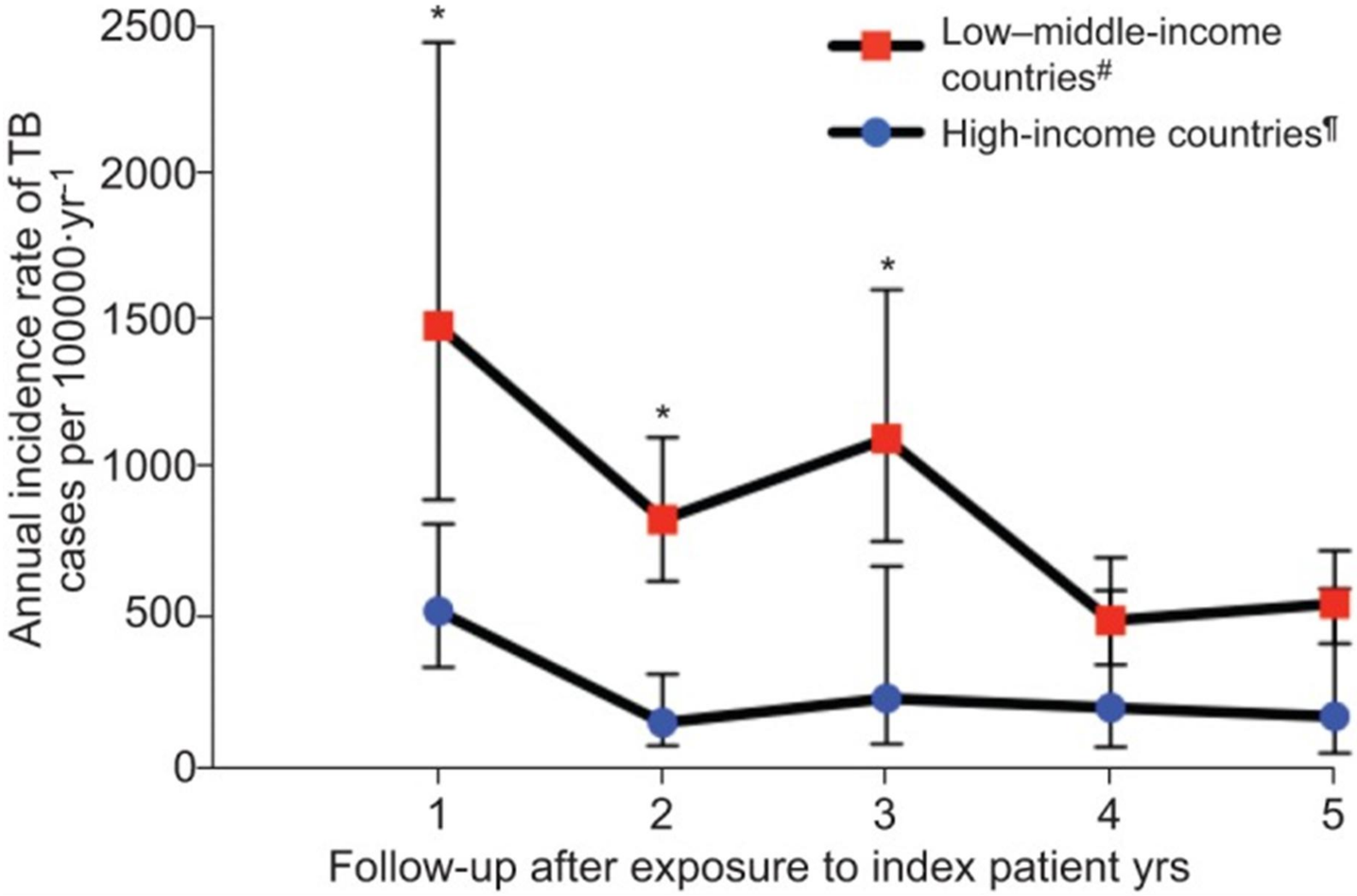

Fox. Eur Resp J, 2013)

Key learnings from consultations with TB vaccine developers

	M72/AS01e	MTBVAC	BNT164
Vaccine type	**Protein/adjuvant**	**Live-attenuated MTB**	**mRNA**
Efficacy target	55%	50%	80%
No. of Doses	2 (1 month apart)	1	3 (0, 2, 6 months)
Phase 2 trials			
Trial phase	2b (completed)	2b (ongoing)	2a (ongoing)
Age range	18-50 years (HIV-ve)	14-45 years (HIV-ve)	≥18 years (HIV+ve & -ve)
Countries	RSA, Kenya, Zambia	RSA, Kenya, Tanzania	RSA, Mozambique
Phase 3 trials			
Progress	Enrolment completed	Planned	Planned
Age range	15-44 years (Includes HIV+ves)	12-65 years (TBC)	-
Population	IGRA+ (& IGRA- for safety and immunogenicity)	IGRA+ (& IGRA- for safety and immunogenicity)	-
Countries	RSA, Indonesia, Kenya, Malawi, Zambia	India	-
Endpoint: primary	Bact +ve sTB	TBD	Bact +ve sTB, Bact +ve, CXR +ve, aTB
Endpoint: secondary	Bact +ve aTB end of follow up		

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Endpoint: secondary	Bact +ve aTB end of follow up		

Key learnings from consultations with TB vaccine developers

- Due to the slow rate of progression to TB disease, licensure trials require large sample sizes and long duration of follow up to demonstrate at least 50% vaccine efficacy and are costly.
- Strategies to reduce the required sample size, duration of follow up, and cost have been applied by TB vaccine developers, which include:
  - Enrolling
    - High incidence age groups
    - In high incidence countries
  - Powering the study to show efficacy among people with evidence of Mtb sensitisation (IGRA positives)
  - Considering using bacteriologically confirmed asymptomatic TB as part of a secondary or composite primary efficacy endpoint with bacteriologically confirmend symptomatic TB

SAGE meeting highlights (1)

SAGE noted that the results of multi-country, multi-region vaccine clinical trials that will only have adequate statistical power to detect efficacy in one or two high tuberculosis burden countries or single-country clinical trials **can be extrapolated to other countries unless there are major epidemiological differences**.

Immunobridging studies, if a suitable correlate of protection is established, or **Phase 4 impact studies may be required to determine effectiveness in other settings** or in priority groups where clinical trials were not sufficient for subgroup assessment.

SAGE meeting highlights (2)

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

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

Asymptomatic tuberculosis

What additional evidence do we need before we can decide on its inclusion in a composite endpoint?

Development of a roadmap & highlights from the SAGE meeting

PDVAC TB session, Dec 2024 (1)

PDVAC Recommendations:

PDVAC endorses the proposal to establish a TAG on clinical and policy considerations for new TB vaccines, to accelerate the testing, approval and recommendation of late-stage candidates, but also cautions the need for continued investment in the early pipeline to mitigate attrition/vaccine failure.

➢ This session: report back on the new TAG and activities 2025

Can PDVAC opine on the pathway to evaluate the feasibility of including asymptomatic TB as an endpoint in future pivotal efficacy trials?

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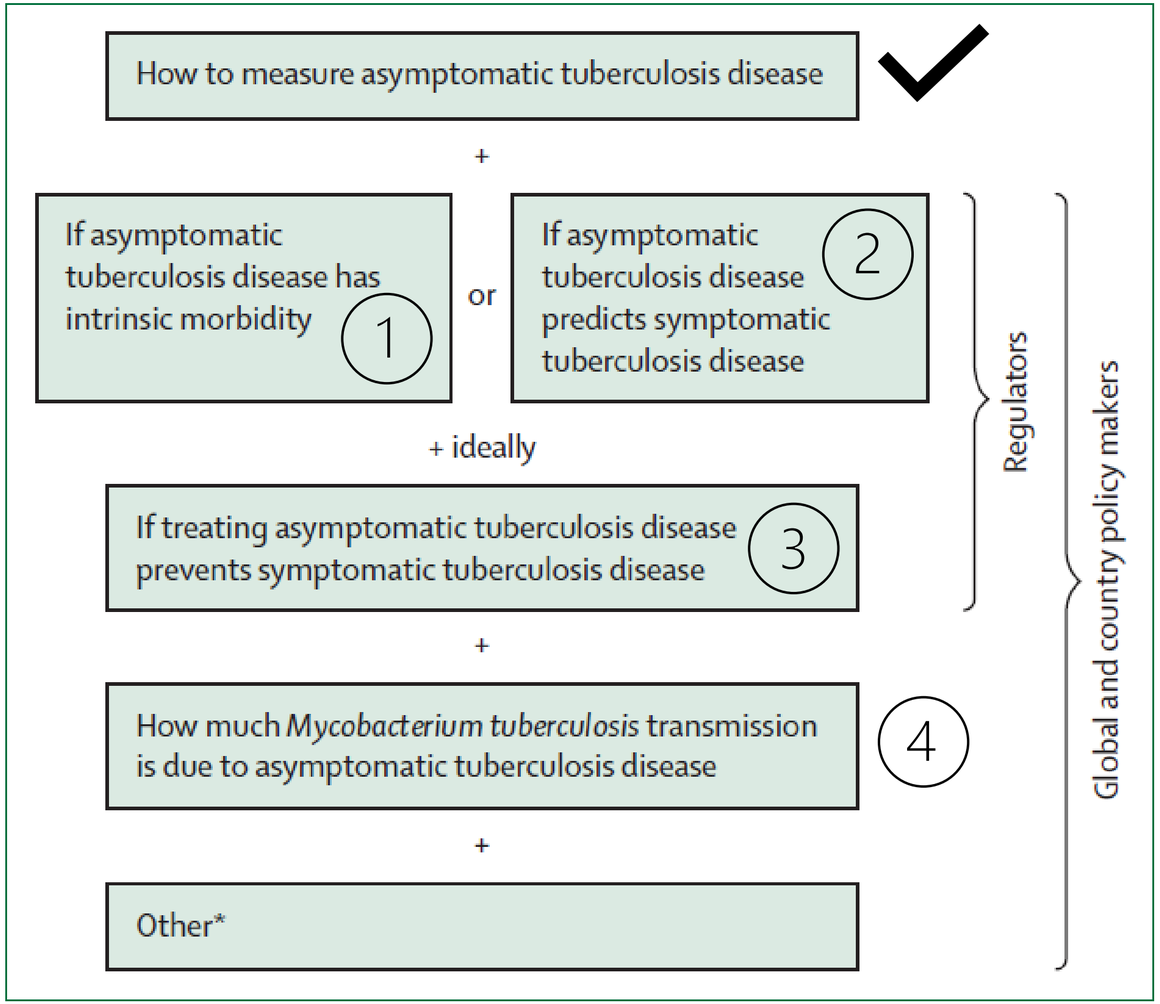
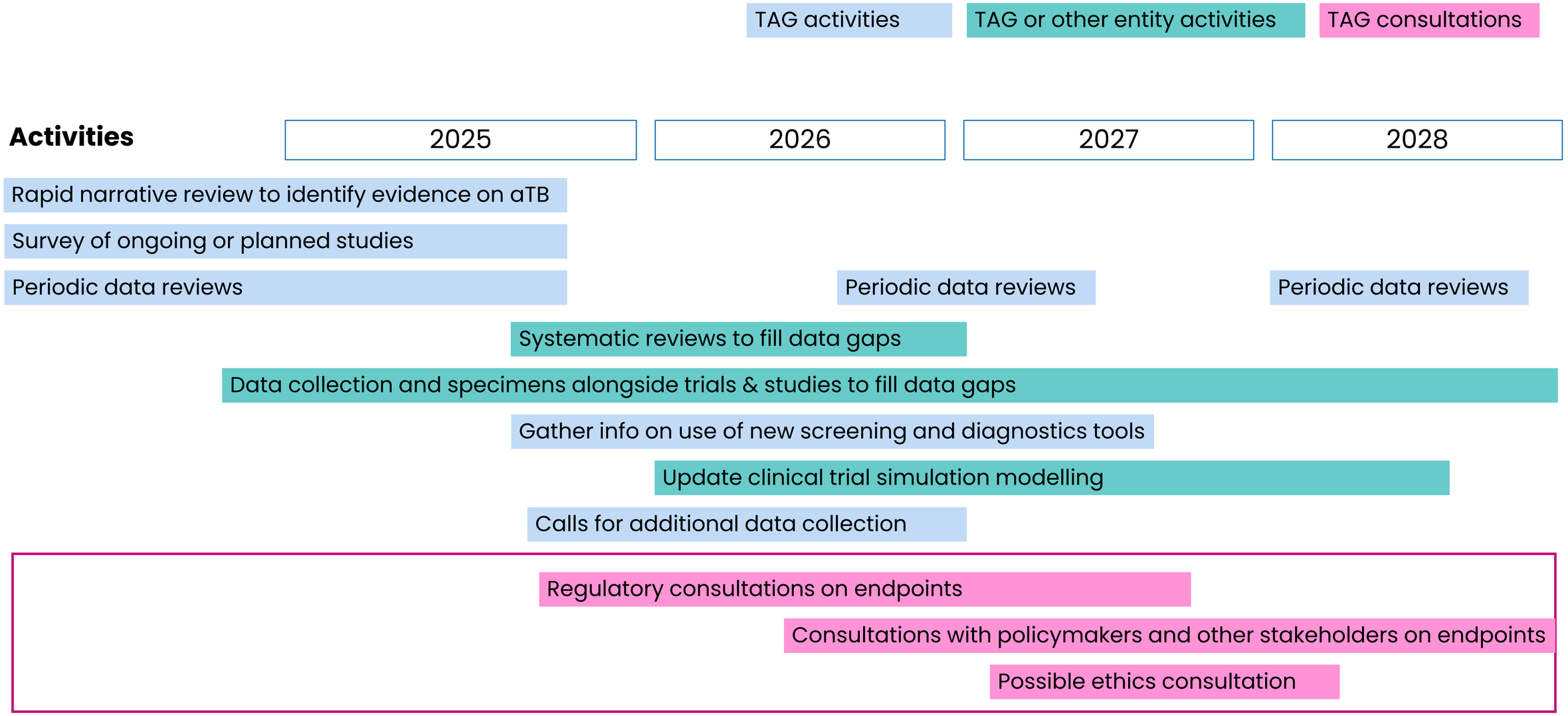
What evidence is required to include bact+ aTB in a composite primary endpoint?



Based on a small, anonymous convience sample of senior regulators and global and country vaccine policy makers.

White et al Lancet Respir Med 2025

Is there support for the proposed steps in the roadmap to evaluate aTB for inclusion in a composite efficacy endpoint?

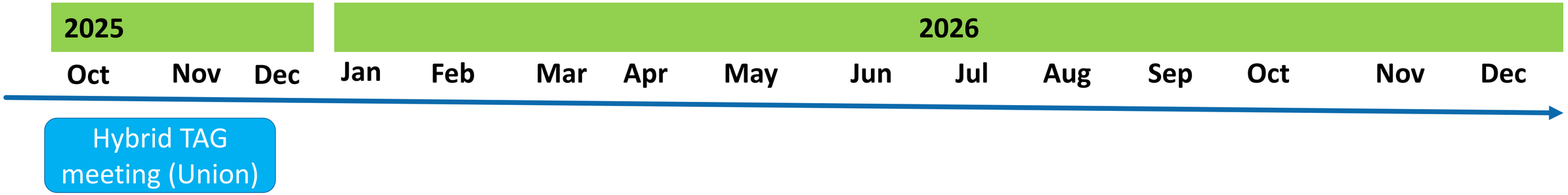


SAGE meeting highlights (3)

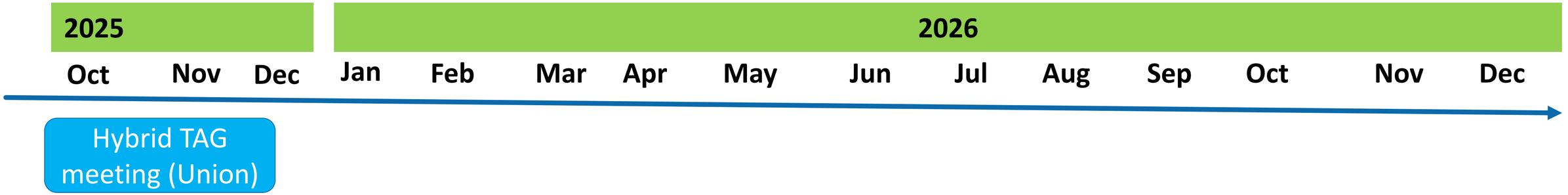
Based on current knowledge, SAGE cautioned that inclusion of asymptomatic tuberculosis as a component of a composite clinical trial endpoint may compromise the demonstration of efficacy against severe tuberculosis, which is considered the most robust strategy for vaccine licensure. Therefore, **SAGE supported the development of a roadmap to generate evidence on the characteristics of asymptomatic tuberculosis to enable decision-making** with regards to the use of composite endpoints in pivotal tuberculosis vaccine trials.

Proposed TAG workplan for 2026

TAG TB vaccines: 2026 workplan

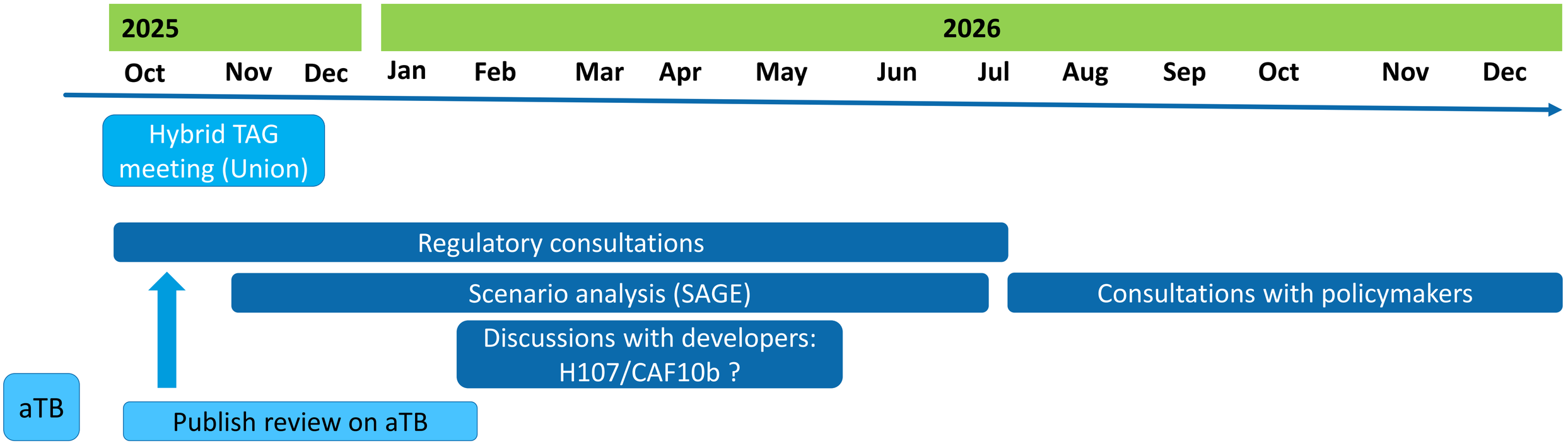


TAG TB vaccines: 2026 workplan



Agenda topic	Speaker
Introduction: Natural history of TB disease, challenges in conducting TB vaccine trials, recap consultations with developers, highlights from SAGE	Gavin Churchyard, Aurum Institute
Evidence needs for including asymptomatic TB in a composite endpoint in TB vaccine trials: activities of the aTB subgroup	Richard White, LSHTM
Innovations in TB vaccine trial design	Mark Hatherill, SATVI
New concepts for efficacy trials, proposals from SSI and BNT	Morten Ruhwald, NIVI
Sample size efficiency of restricting participation in tuberculosis vaccine trials to interferon-gamma release assay-positive participants	Frank Cobelens, AIGHD, *TBC*
Controlled human infection models	TBD
High risk populations (people deprived of liberty, miners)?	Julio Croda
Next steps for the TAG: planning for 2026 e.g. convenings with regulators, policymakers, other stakeholders; scenario development	Discussion, All

TAG TB vaccines: 2026 workplan



Proposed TAG workplan for 2026

Are there are other activities that PDVAC recommends?

What are PDVACs thoughts on the scenario planning?

Acknowledgements

- WHO TAG on Evidence for Clinical and Policy Considerations for New Tuberculosis Vaccines
- Vaccine developers who met with the TAG
- SAGE members & SAGE secretariat
- Gates Foundation & Wellcome Trust

Asymptomatic Tuberculosis

TAG aTB subgroup members

Richard White

Gavin Churchyard

Kristin Nelson

Willem Hanekom

Mark Hatherill

Rumina Hassan

Giovanni Sotgiu

Akbar Fotouhi

Morten Ruhwald

Sonali Kochhar

WHO

Gitte Giersing

Dennis Falzon

Other experts

Frank Cobelens

Clara Suner

Charlotte Doran

Alberto Garcia-Basteiro

New TB vaccines for adults and adolescents

Update from the Finance & Access WG

World Health Organization | IVB

Product Development for Vaccines Advisory Committee (PDVAC)

7 October 2025

In 2025, WHO launched the global Finance & Access Working Group

World Health Organization

Progress update report of the TB Vaccine Accelerator Council: November 2024-February 2025

24 April 2025 | Meeting report

2. Establishment of the finance and access working group

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

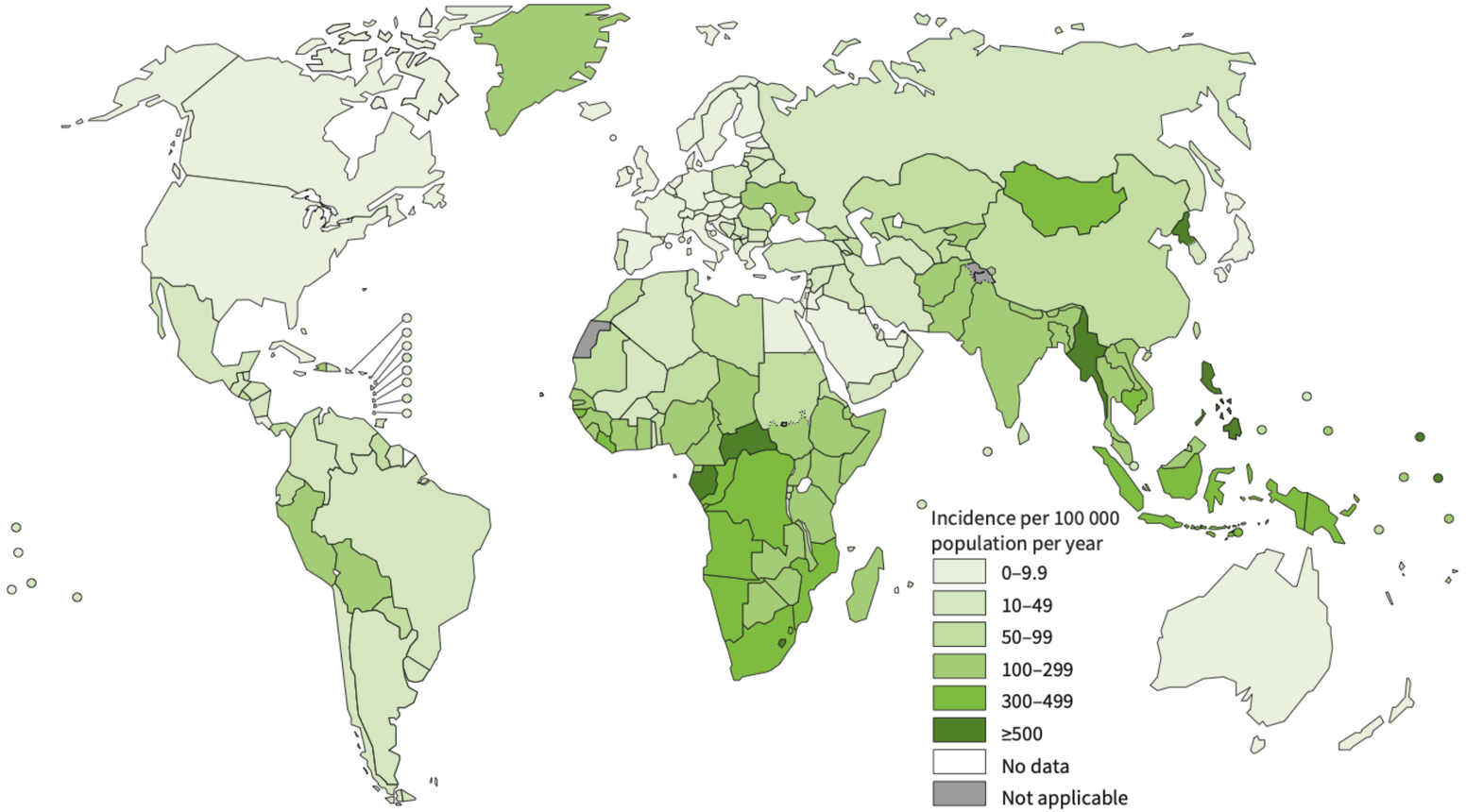
The finance and access working group was established in February 2025.

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

Progress update report of the TB Vaccine Accelerator Council: November 2024-February 2025

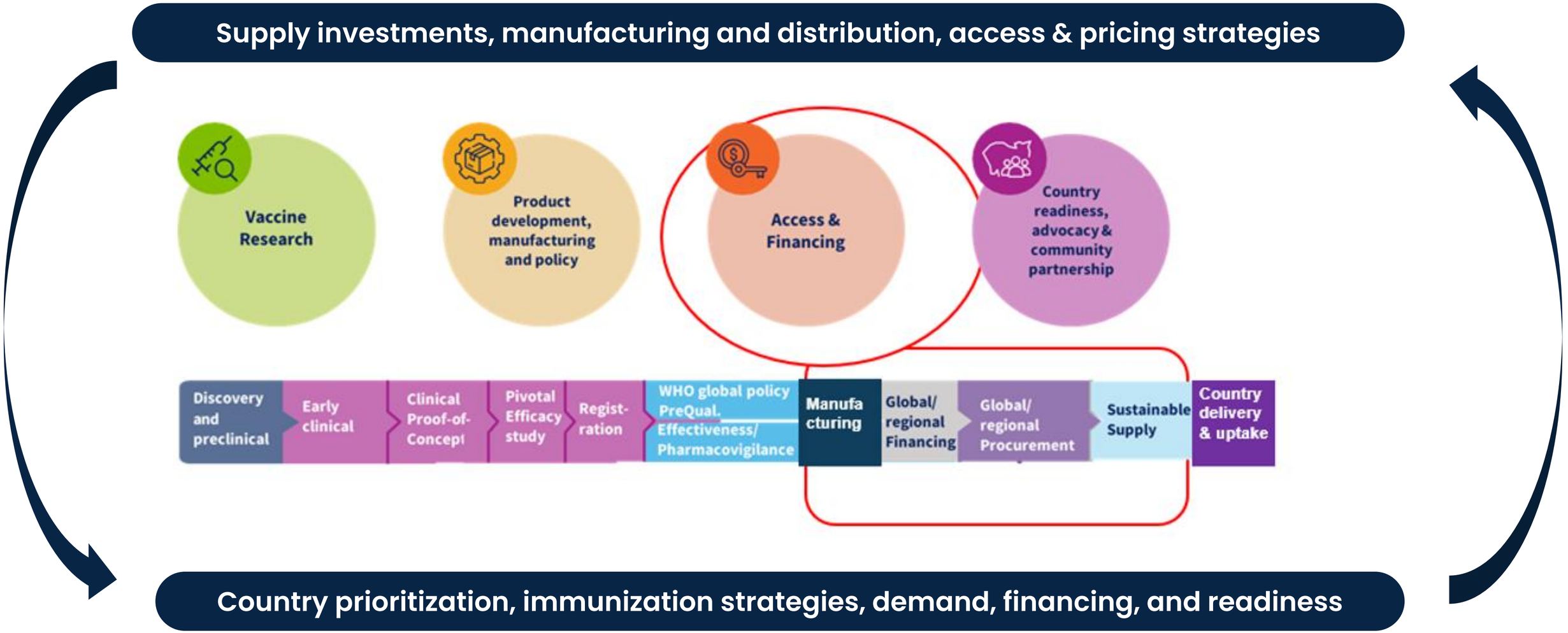
Co-convened by **WHO, Gavi and the Government of South Africa**

Equitable access to novel TB vaccines in low- and middle-income countries is a priority



Map is showing estimated TB incidence rate in 2023 (Global TB Report, 2024)

Importance of early access and financing considerations



Finance and Access Working Group – Vision and Terms of Reference

Objective:

To promote timely, equitable and sustainably financed access to affordably priced new TB vaccines in all countries where there is demand for these vaccines, driven by public health need, fostering sustainable supply

Goals

2025

- Develop an early understanding of anticipated barriers, bottlenecks, challenges and supply-demand dynamics relevant to country financing and access for novel TB vaccines
- Accelerate the identification of financing and access solutions and opportunities to incentivize equitable and affordable global access
- Develop a financing and access options framework, outlining mechanisms that enable countries to have timely and sustainable access to novel TB vaccines
- Coordinate efforts across governments, partners, financing institutions, private sector, and civil society to propose strategic partnerships and financing and access mechanisms with global applicability, while maintaining a particular focus on speeding up vaccine availability and access for high TB-burden countries

2026 +

- Foster the design, development and implementation of financing and access solutions that enable countries to have timely and sustainable access to safe, effective, and affordably priced TB vaccines.

Finance and Access Working Group Members List

Co-Conveners

Norbert Ndjeka
Chief Director – TB Control and Management, National Department of Health

Lindiwe Mvusi
Director – TB Control and Management, National Department of Health

Dominic Hein
Director – Market Shaping, Gavi, the Vaccine Alliance

Marion Menozzi-Arnaud
Senior Specialist – Market Shaping, Gavi, the Vaccine Alliance

Tiziana Scarna
Senior Manager – Market shaping, Gavi, the Vaccine Alliance

Tara Lavanya Prasad
Team Lead – Vaccine Global Access, Immunization, Vaccines and Biologicals department, WHO

Matteo Zignol
Unit Head – Prevention, Diagnosis, Treatment, Care & Innovation, Global Programme on Tuberculosis and Lung Health, WHO

Permanent members

Santiago Cornejo
Executive Director, Revolving Fund for Access to Vaccines, Pan American Health Organization *(alternate: Murat Ozturk, Supply Chain Advisor)*

Dinesh Arora
Principal Health Specialist, Asia Development Bank

Cristina Niculesc
Life Science Investment Specialist, EIB *(alternate: Valeria Iansante, Life Science Specialist)*

Nicolas (Nick) Menzies
Associate Professor of Global Health, Harvard TH Chan School of Public Health

Richard White
Professor of Infectious Disease Modelling, London School of Hygiene and Tropical Medicine

Mike Frick
Co-Director, Tuberculosis project, Treatment Action Group

Andrew Jones
Deputy Director, UNICEF Supply Division Vaccine Centre *(alternate: Kristina Lorensen, Senior Contract Manager)*

Eliud Wandwalo
Head, TB, Global Fund to Fight AIDS, TB and Malaria *(alternate: Grania Brigden, Senior TB Advisor)*

Frauke Uekermann
Director, Vaccine Markets, Clinton Health Access Initiative *(alternate: Verena Damovsky, Clinton Health Access Initiative)*

Abebe Genetu Bayih
Ag. Lead Local Manufacturing of Health Commodities, Africa Centres for Disease Control and Prevention

Erlina Burhan
Pulmonologist, Head of TB Expert, Coalition Against TB Faculty of Medicine, Universitas Indonesia – Persahabatan Hospital

Dauda Foday Suma
Principal Industrial/Manufacturing Development Officer, Africa Development Bank

Ana Liza Hombrado Duran
Director, Research Institute for Tropical Medicine

Éder Gatti
Director, National Immunization Program

Bonanza Perwira Taihitu
Senior Advisor to Minister of Health, Politics and Global Health

Guy Pickles
Head of Vaccines, MedAccess *(alternate: Gillian Leitch, Head, HIV, TB and Antimicrobial Resistance)*

Other knowledge partners (not exhaustive)

High-level 2025 workplan

Calls and Meetings

Bi-weekly co-lead calls

Monthly F&A WG calls

Jan 2025 — Dec 2025 — 2026 +

Deliverables and Milestones

- Vision & milestones defined (WHO)
- Analysis of licencing agreements and access provisions (WHO)
- Map 5 country specific access & financing plans (WHO)
- Map financing sources, needs & gaps (WHO)
- Develop supply & demand forecasts (Gavi)

These deliverables will inform the WG's work on subsequent deliverables

- Identify key gaps and root causes
- Propose financing and access solutions & actions
- High-level summit & follow up

Design, development and implementation of financing and access solutions

Consultation with agencies

- Regional / Multilateral Development Banks
- Bilateral / Multilateral agencies
- Vaccine developers, regulators, and market stakeholders
- PDPs
- WG partners, expert groups
- NGOs and Foundations
- Civil Society
- Public Health organizations
- SRAs
- Industry Players

Consultation with countries and regions

World Health Organization – African Region; Americas Region; Eastern Mediterranean Region; Regional Office for Europe; Regional Office for South-East Asia; Regional Office for the Western Pacific

South Africa, Philippines, Indonesia, Brazil, Ethiopia

High-TB burden countries from different regions represented in the TB vaccine accelerator council

High-TB burden country from SSA

Key technical analyses of Finance and Access Working Group

Product insights

Analysis of late-stage licencing agreements and access provisions

Licensing and access strategies for TB vaccine candidates are crucial for equitable distribution, geographically diverse manufacturing and long-term supply sustainability

Country insights

Map 5 high-burden country access & financing plans

Gain insights into country-specific demand for introducing new TB vaccines and scaling up demand over time, financial commitments to new TB vaccines, and potential barriers or conditions for access

Financing insights

Map global external and domestic financing sources, needs & gaps

To ensure sustainable immunization programmes, it is essential to identify any financing gaps for vaccine procurement, to develop early solutions to fill these gaps and accelerate access

Market insights

Develop global 10-year supply & demand forecasts

To understand demand-supply gap and investigate if early market shaping is needed to ensure an impactful global launch and roll-out of novel tuberculosis vaccines for adolescents and adults

Key stakeholder engagements in 2025

20th May 2025

3rd meeting of the TB Vaccine Accelerator Council on May 20, 2025

[Tuberculosis Vaccine Accelerator Council]

28th May 2025

Civil Society Information Session: Finance and Access Working Group of the WHO TB Vaccine Accelerator Council

28 May 2025 14:00 – 15:00 CET

Civil Society Information Session:

Finance and Access Working Group of the WHO TB Vaccine Accelerator Council

When: 28 May 2025, 14:00H – 15:00H CEST

[Civil Society Information Session: Finance and Access Working Group of the WHO TB Vaccine Accelerator Council]

13th June 2025

Ensuring sustainable financing and equitable access to novel TB vaccines

13 June 2025 09:30 – 12:00 SAST | Johannesburg, South Africa

On the sidelines of the Fourth G20 Health Working Group meeting in Johannesburg, South Africa, the Government of South Africa and the World Health Organization will co-host the side-event "Ensuring sustainable financing and equitable access to novel TB vaccines" on 13 June 2025.

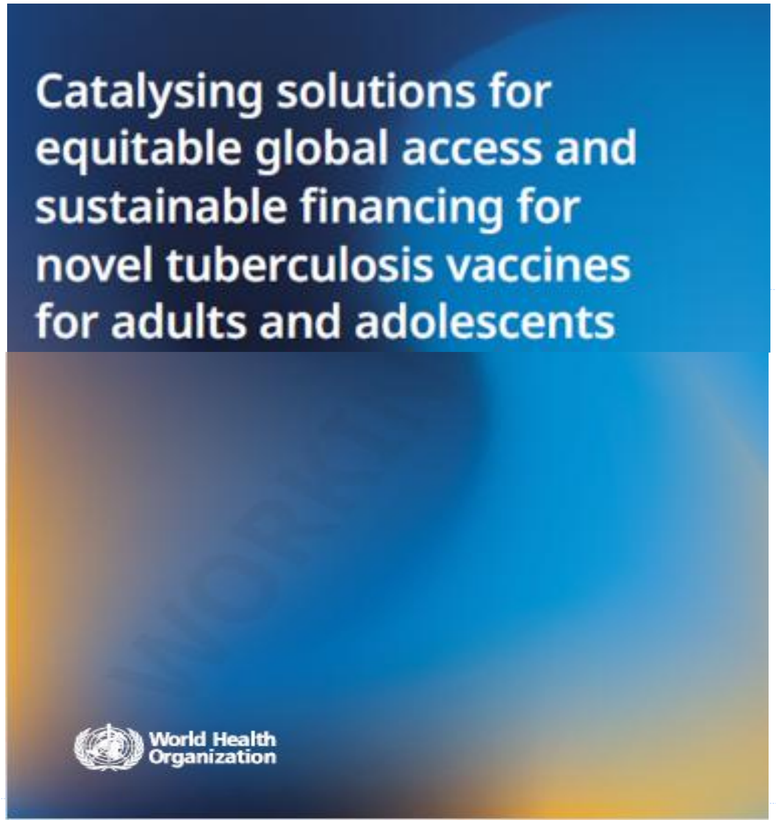
TB remains a significant global health and development challenge. Each year, over 10 million people contract TB, and more than 1 million lose their lives to the disease. Alarmingly, at least 70% of these cases and deaths occur in G20 countries and regions. While technological innovations—such as the development of new TB vaccines—are essential to meeting global TB targets, progress has been hindered by persistent scientific hurdles and a chronic lack of investment in research and product development.

The only approved TB vaccine, Bacille Calmette-Guerin (BCG), offers some protection for infants and young children but doesn't adequately protect adolescents and adults—who are most likely to spread the disease. New vaccines being developed for these age groups could help stop the spread of TB and save lives, especially if they are affordable and fairly distributed around the world.

G20 SOUTH AFRICA 2025 World Health Organization

[Ensuring sustainable financing and equitable access to novel TB vaccines]

Towards launch at a high-level summit on financing & access for novel TB vaccines



Launch Event

2025 G20 Health Working Group Ministerial Meeting on November 6th in South Africa

- Launch a **shared vision and goal for novel TB vaccine equitable access**
- Launch the **TB vaccine finance and access report**, **outlining solutions** to help countries gain timely, reliable access to safe, effective, and affordably priced new TB vaccines
- **G20 ministerial declaration** of commitment and support
- G20 members verbally **highlight political commitment** and propose priority areas of action

Next steps

- **Commitment from key partners on their respective role**
- **Design, development and implementation of financing and access solutions** through the F&A WG and with key stakeholders
- **Finance and Access Stakeholder Forum** meeting bringing together different stakeholders

Thank you

For any questions, please contact:

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