Prioritising the preparedness to introduce new TB vaccines into Africa

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Global TB Situation

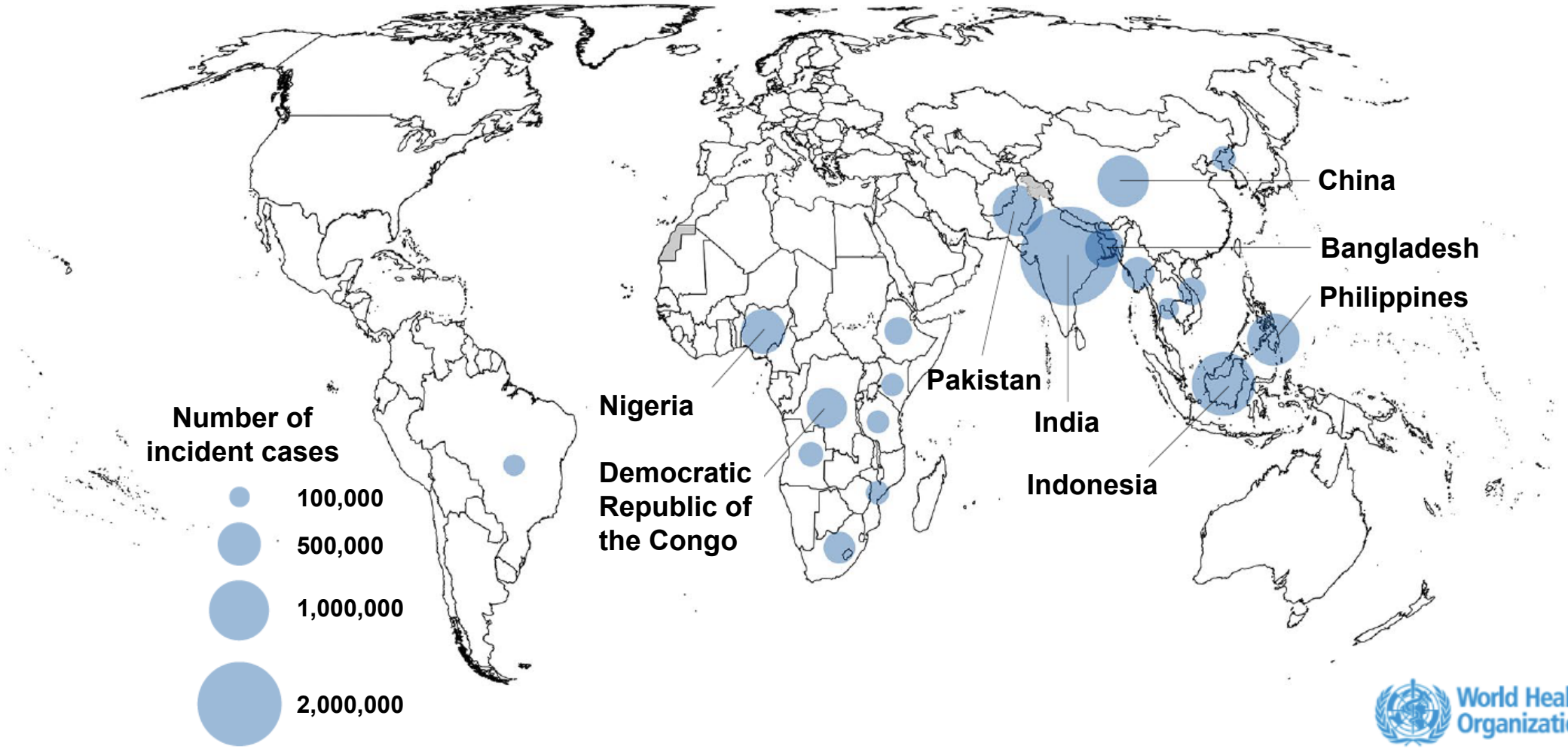
A quarter of the world's population has been infected with TB bacilli.

	Estimated incidence	Estimated deaths
All forms of TB, 2024	10.7 million (9.9–11.5 million) 54% men | 11% <15y	1.08 million* (0.99–1.2 million)
HIV-associated TB, 2024	619,000 (545,000–698,000)	150,000 (120,000–183,000)
MDR/RR-TB, 2024	390,000 (360,000–430,000)	150,000 (93,000–210,000)

World Health Organization

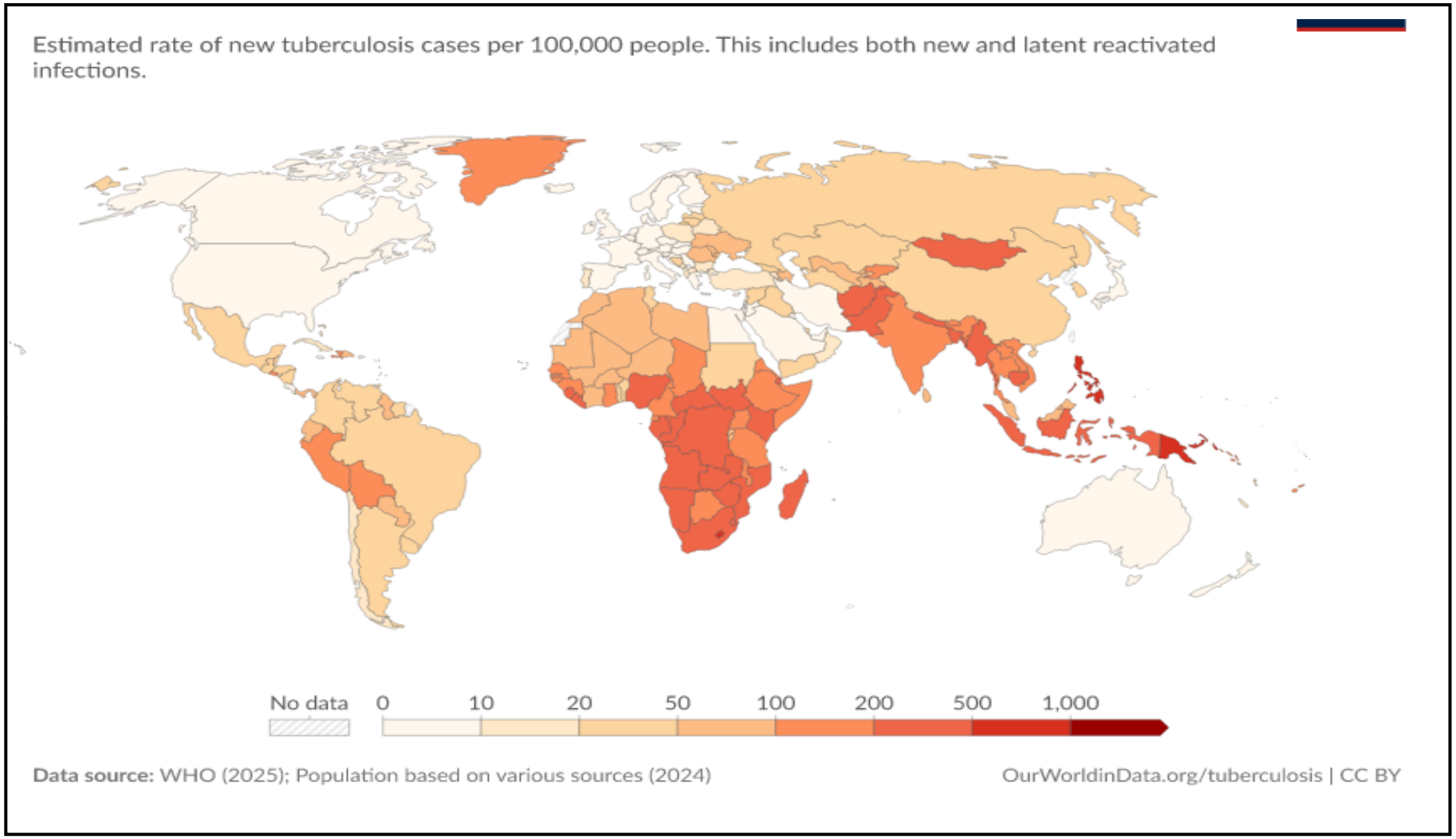
TB Burden: 8 countries, 67% of global cases in 2024

87% in 30 high TB burden countries



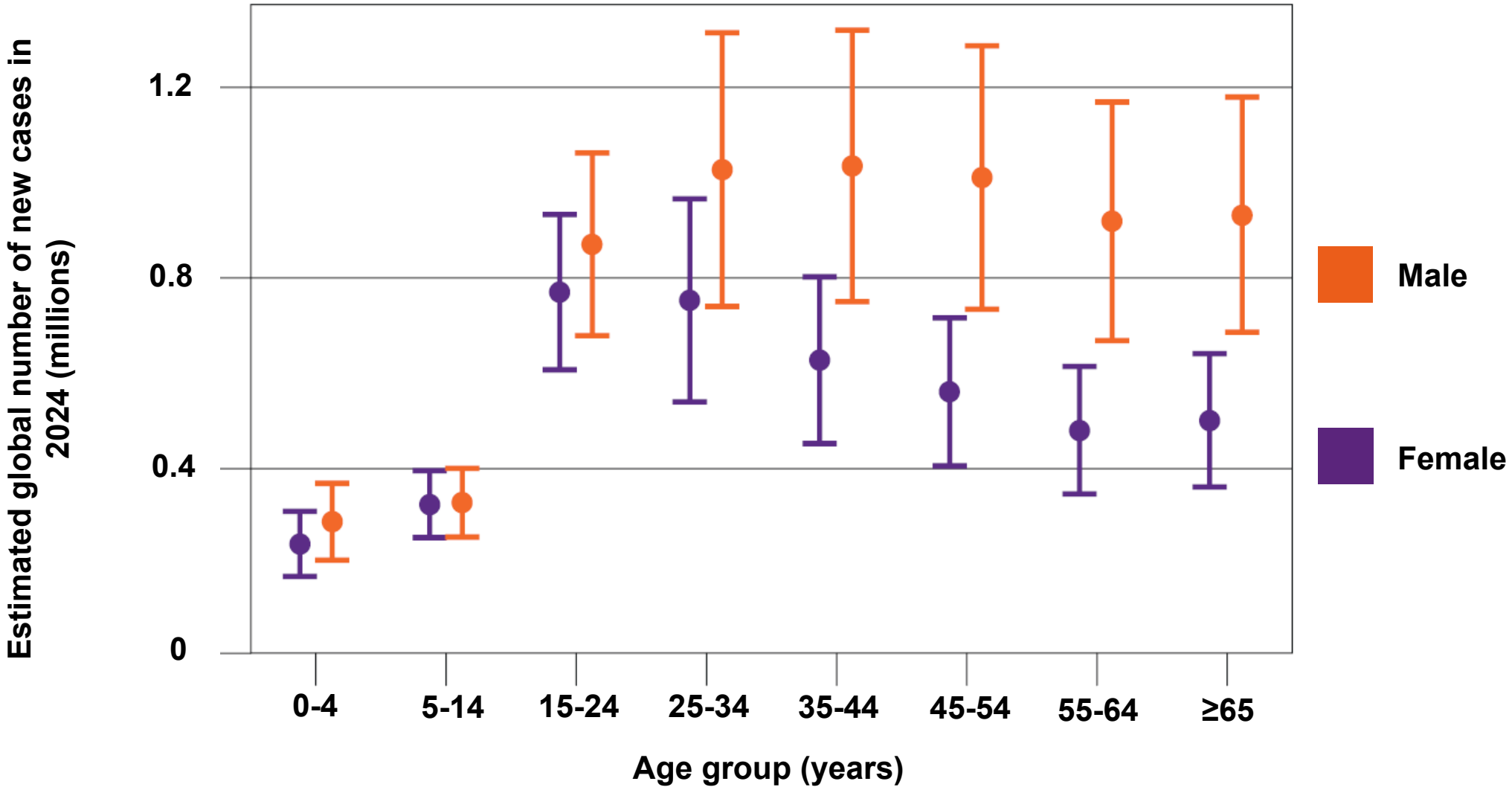
WHO: TB is the leading cause of death globally from a single infectious agent.

Rate of new TB cases, 2024



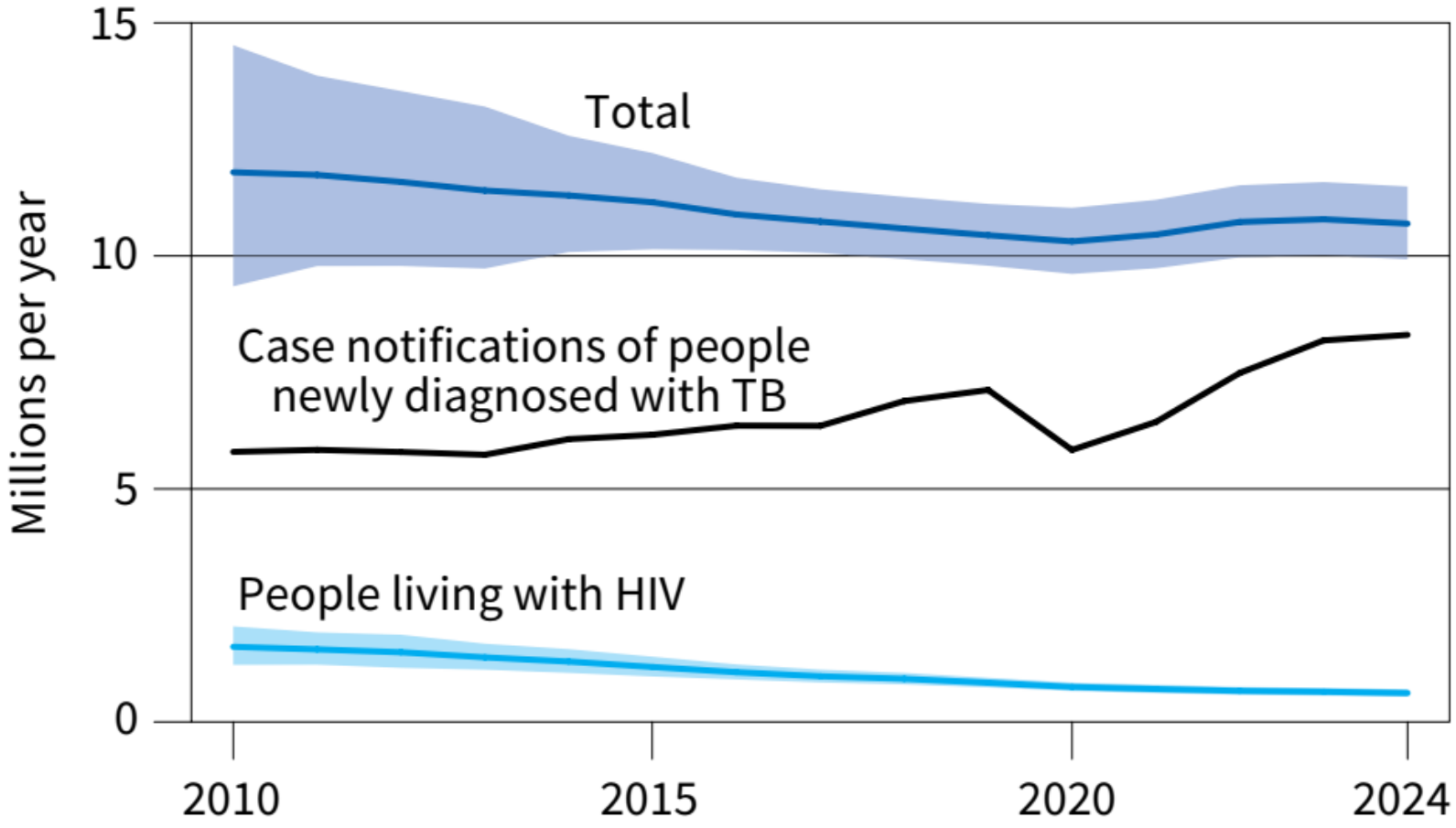
Most TB cases among adults, more men than women

Globally: 54% men, 35% women, 11% children & young adolescents (<15 years)



World Health Organization

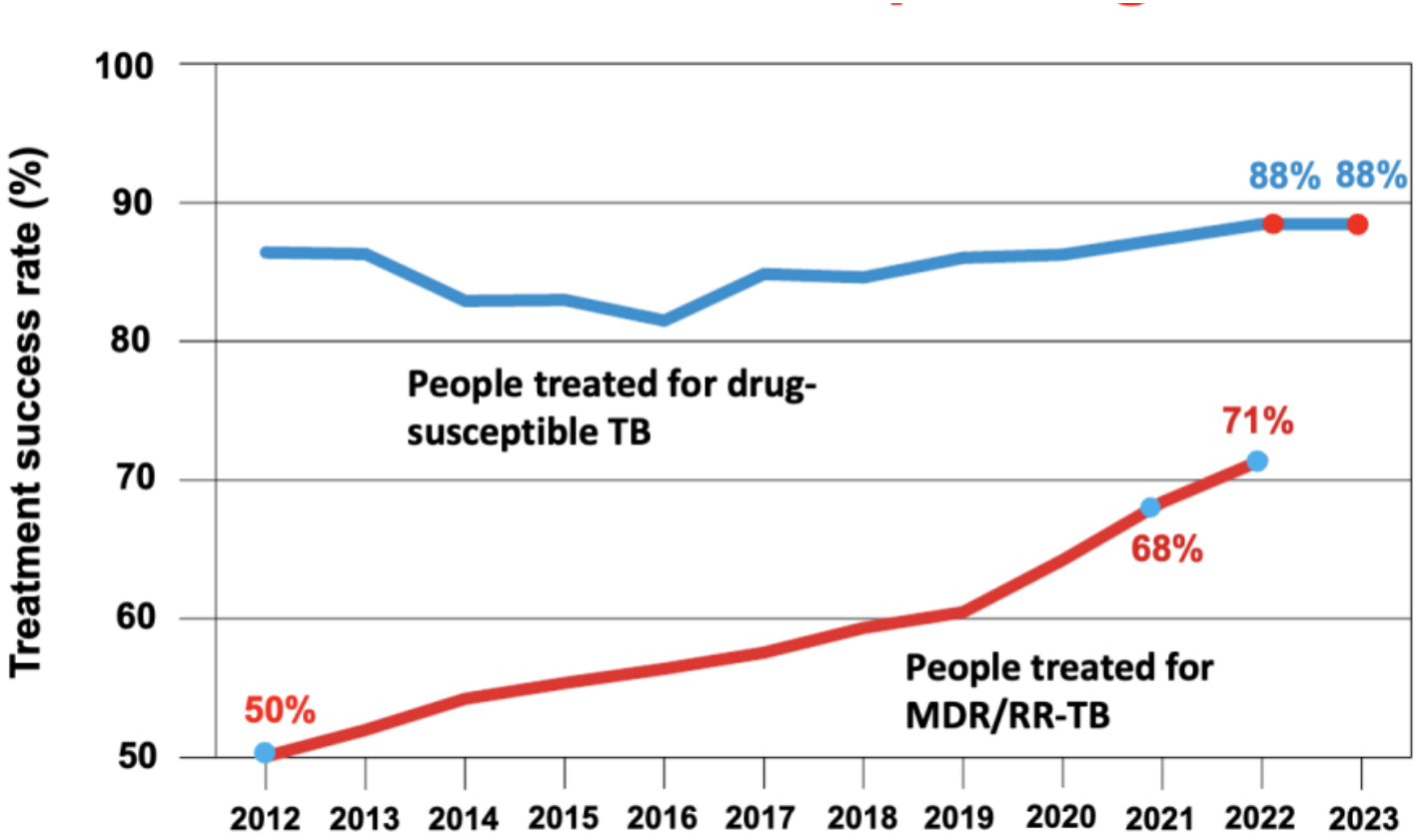
Estimated TB incidence and reported new TB cases



Shaded area shows the 95% uncertainty interval

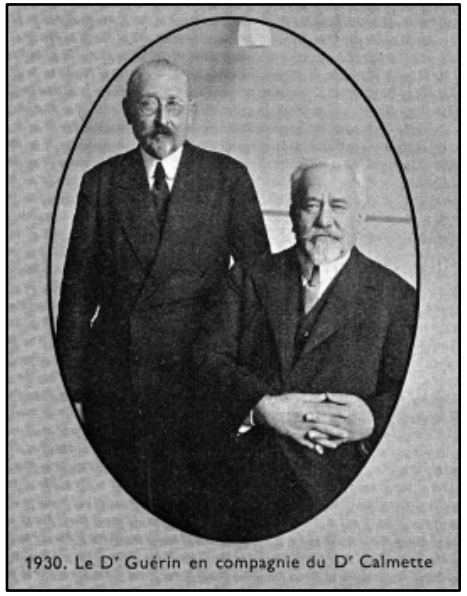
Treatment success rates at global level

Sustained or improving



TB Vaccines: From BCG to the Present

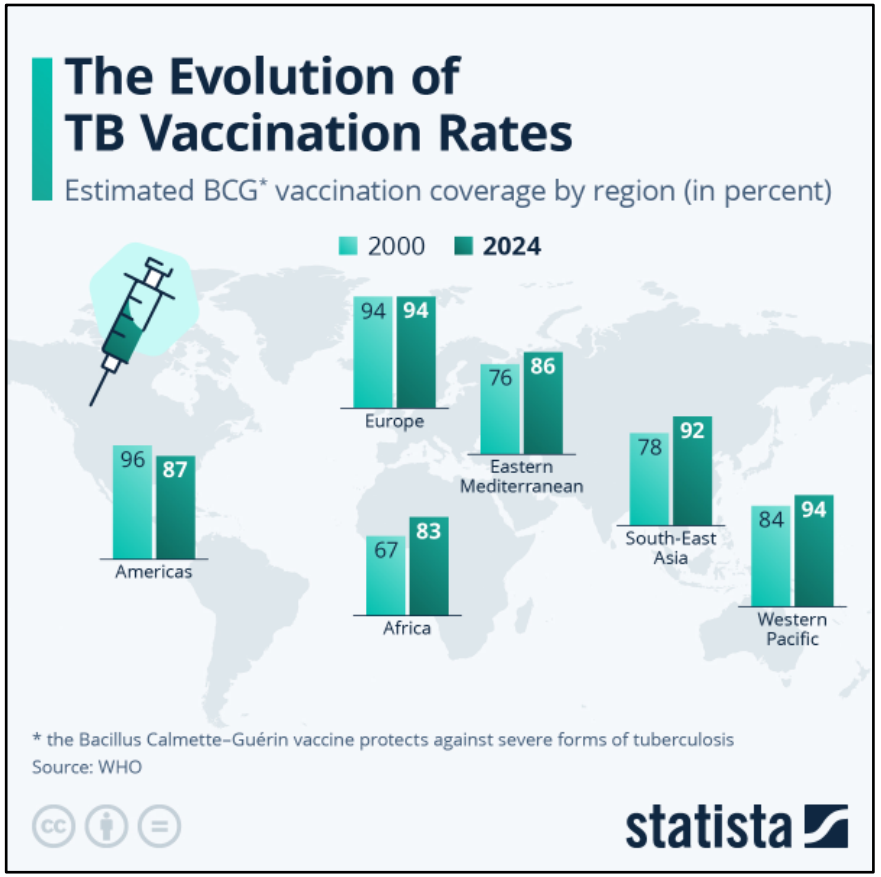
- 1908–1921: Albert Calmette & Camille Guérin develop BCG through repeated subculture and attenuation of *Mycobacterium bovis*
- 1921: First human Bacille Calmette Guerin (BCG) vaccination administered to an infant in Paris
- 1974: BCG incorporated into WHO's Expanded Programme on Immunization



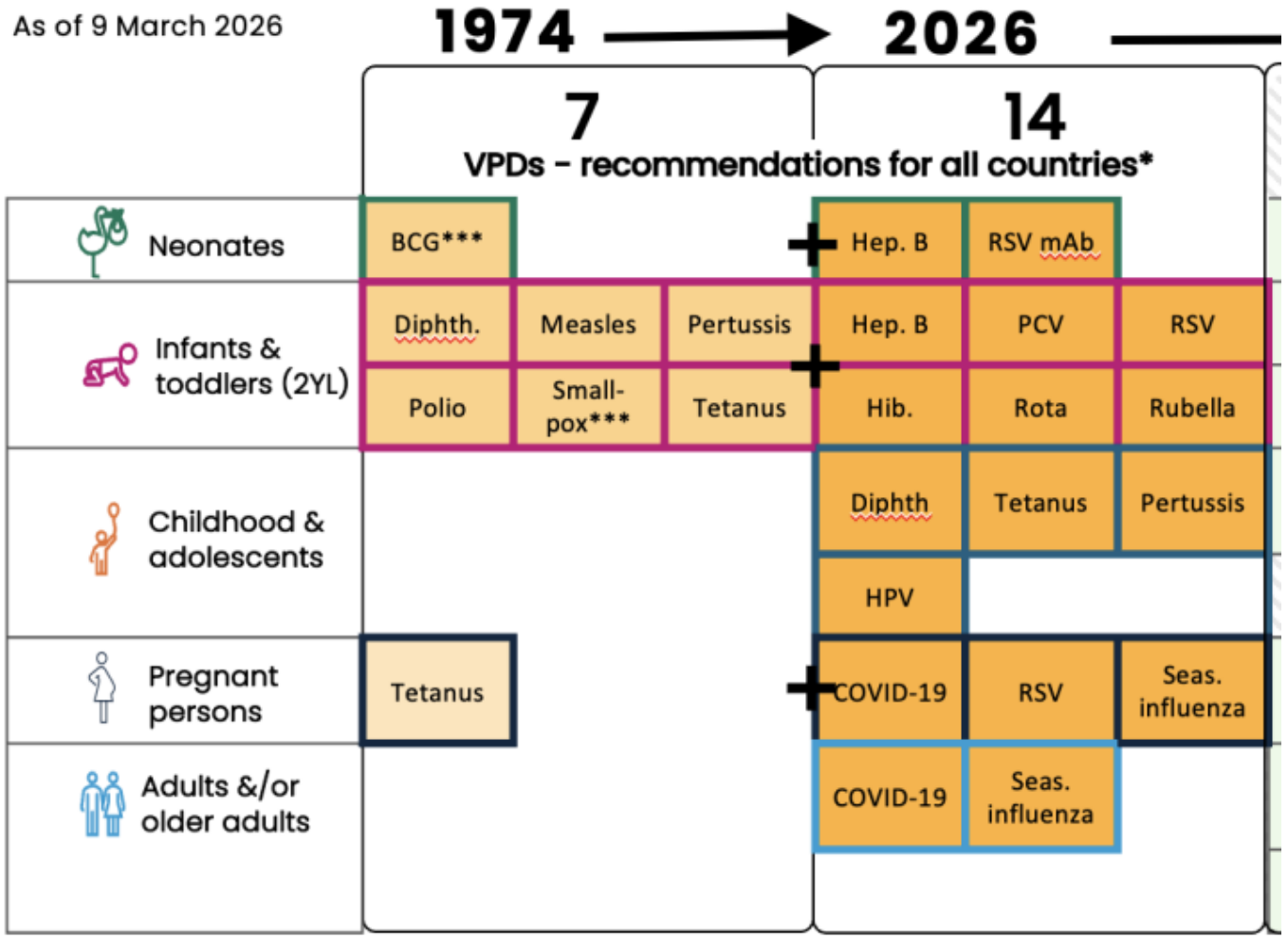
L'Institut Pasteur de Lille

TB Vaccines: From BCG to the Present

- Today: BCG remains the only licensed TB vaccine and remains valuable
- Major strength: Protects infants and young children against severe/disseminated TB and TB meningitis
- Major limitation: Variable protection against pulmonary TB in adolescents and adults
- A century later: Multiple next-generation TB vaccines are now in advanced clinical development



WHO: Universal BCG at birth in high-TB-burden settings, Low-incidence countries adopt selective, risk-based vaccination



WHO, IVB Director Report, 2026

2026: Transformative clinical development pipeline built on genetics, immunology, vaccine platforms and disease epidemiology

Table 6.4 The global clinical development pipeline for new TB vaccines, August 2025[a]

Phase I	Phase IIa	Phase IIb	Phase III
RH119 Wuhan Ruiji Biotechnology Co., Ltd	ChAdOx185A-MVA85A University of Oxford	DAR-901 booster Dartmouth, St. Louis University	GamTBvac Ministry of Health, Russian Federation
AdHu5Ag85A McMaster	ID93 + GLA-SE(QTP101) Quratis U.S. NIH/NIAID	RUTI Archivel Farma, S.L.	MIP/Immuvac ICMR, Cadila Pharmaceuticals
H107e/CAF®10b Statens Serum Institut	AEC/BC02 Anhui Zhifei Longcom		M72/AS01E GSK, Gates MRI
Ad5-105K CanSino	BNT164a1 BioNtech SE		MTBVAC Biofabri, University of Zaragoza, IAVI, TBVI
	BNT164b1 BioNtech SE		VPM1002 SIIPL, VPM
	TB/FLU-05E RIBSP		BCG vaccination to prevent infection (TIPI) HJF

Legend

- Messenger RNA (mRNA)
- Viral vector
- Protein/adjuvant
- Mycobacterial – inactivated
- Mycobacterial – live attenuated

An example:
Re-engineering BCG to provide better protection

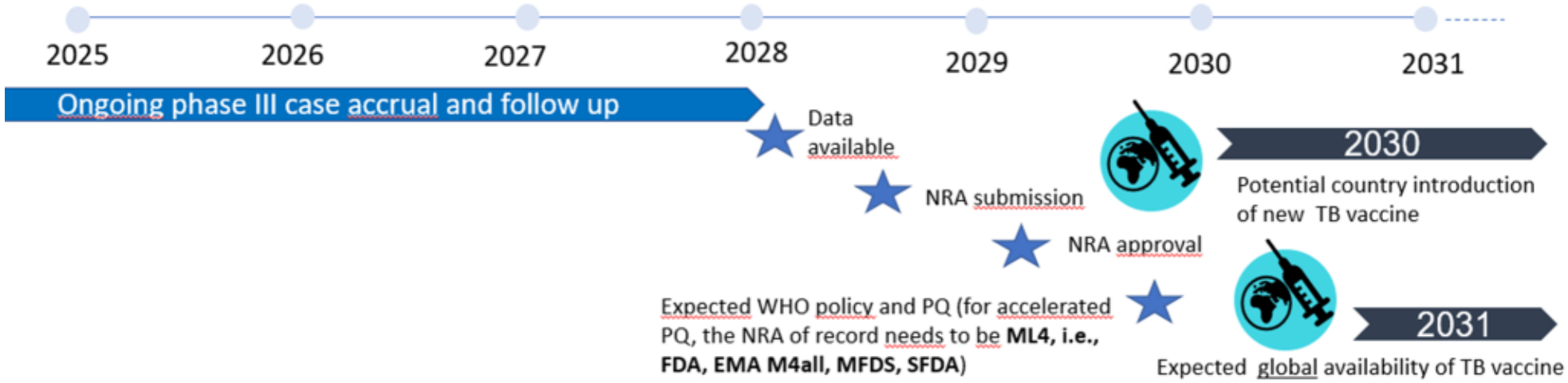
Why modify BCG?	**What has been changed?**	**What has been observed?**	**What does this mean now?**
Conventional BCG has bacterial cell-wall features that can limit recognition by the innate immune system	BCG has been genetically engineered (rBCG) to expose normally masked bacterial signals and enhance innate immune recognition	Enhanced NOD1-mediated immune responses and improved protection against M. tuberculosis in preclinical models	Provides a biological rationale for further development, but clinical safety, immunogenicity and efficacy still need to be established

Bavesh Kana, Wits School of Pathology and TB Research Unit

M72/AS01E and MTBVAC are the leading late-stage candidates intended for global use.

Candidate	Platform	Current status	Pre-2030 perspective
M72/AS01E	Protein + adjuvant	Phase III	Key candidate for global use; Phase III programme across multiple high-burden countries
M72 Phase IIb trial showed approximately **50% efficacy against progression to pulmonary TB disease** among *M. tuberculosis*-infected adults			
MTBVAC	Live attenuated M. tuberculosis	Phase III	Late-stage candidate; being developed across populations, including infants and adolescents/adults
VPM1002	Recombinant BCG	Phase III	Could potentially achieve national-level approval, depending on trial results
GamTBvac	Protein + adjuvant	Phase III	Potential national-level approval, particularly based on Russian Federation programme
MIP / Immuvac	Inactivated M. indicus pranii	Phase III	Late-stage programme, particularly relevant to India

2031: Expected global availability of TB Vaccine



- Several candidates targeting adolescents and adults in Phase III
- Delivery platform for new target population is required
- Need to understand evidence needs to inform timely policy recommendations
- Need for provisions in place for equitable access
- Need to build Vaccine acceptance with communities

Implementing new health interventions in developing countries: Why do we lose a decade or more?

Percentage of LICs and LMICs implementing interventions after 5, 10, and 15 years

	5 years		10 years		15 years	
	LIC	LMIC	LIC	LMIC	LIC	LMIC
Hepatitis B	0%	6%	3%	24%	10%	41%
***Haemophilus influenzae*type B**	0%	0%	3%	0%	15%	26%

BMC Public Health
Link to BMC Public Health

Brooks A et al, 2012

TB Vaccine Accelerator — Country Readiness to prevent delays

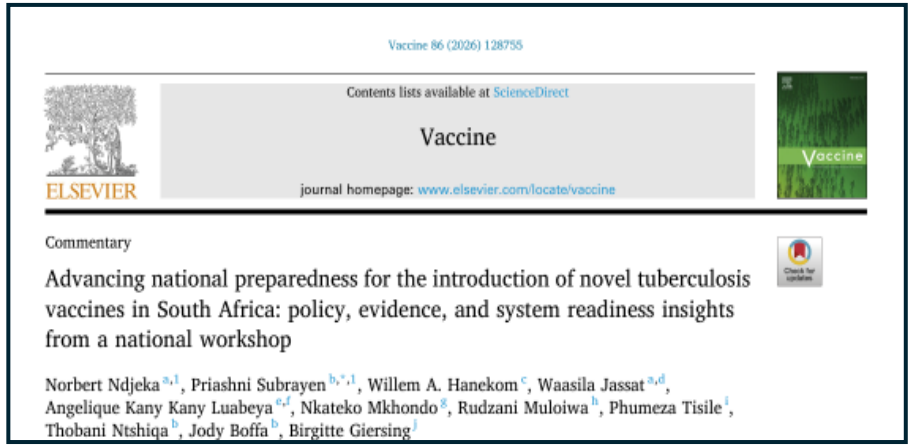
- Purpose: Prepare countries for rapid, equitable introduction and scale-up
- Demand & policy: Build evidence needed for national decision-making
- Delivery readiness: Select target population and introduction strategies: consider adolescents and adults
- Systems readiness: Assess delivery platforms, workforce, cold chain, surveillance, safety monitoring and data systems
- Financing & access: Costing, financing, procurement, sustainability
- Community engagement: Awareness, influencers, confidence, demand, addressing hesitancy and barriers to access
- Equity: High-TB-burden countries and populations must be prioritised

Countries with TB Vaccine Readiness Activity

Country	Readiness activity	Timing/status
🇮🇩 **Indonesia**	First prototype **country preparedness workshop**	**Nov 2024**
🇿🇦 **South Africa**	National **country preparedness workshop**; subsequently established vaccine implementation/research task-force activity and a Novel TB Vaccines Preparedness Consortium	**Jul 2025 – ongoing**
🇰🇪 **Kenya**	Joint WHO country-preparedness workshop; development of national roadmap/actions	**Jun 2026**
🇲🇼 **Malawi**	Participated in joint preparedness workshop; roadmap/actions initiated	**Jun 2026**
🇿🇲 **Zambia**	Participated in joint preparedness workshop; roadmap/actions initiated	**Jun 2026**
🇧🇷 **Brazil**	Country preparedness meeting	**Planned for Nov 2026**

Policy to Evidence convening, South Africa, 2025
'A Preparedness Workshop'

- Political, funder, activist leadership
- Govt (NTP, EPI, regulators, logistics, finance), NITAGs, civil society organizations, M72 trial PIs, researchers, donors, international partners
- Engagement of people with lived experience of TB
- Evidence gaps and implementation research
- Roadmap for Accelerated Implementation of Novel TB Vaccines for Adults and Adolescents in South Africa


Vaccine 86 (2026) 128755

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Commentary

Advancing national preparedness for the introduction of novel tuberculosis vaccines in South Africa: policy, evidence, and system readiness insights from a national workshop

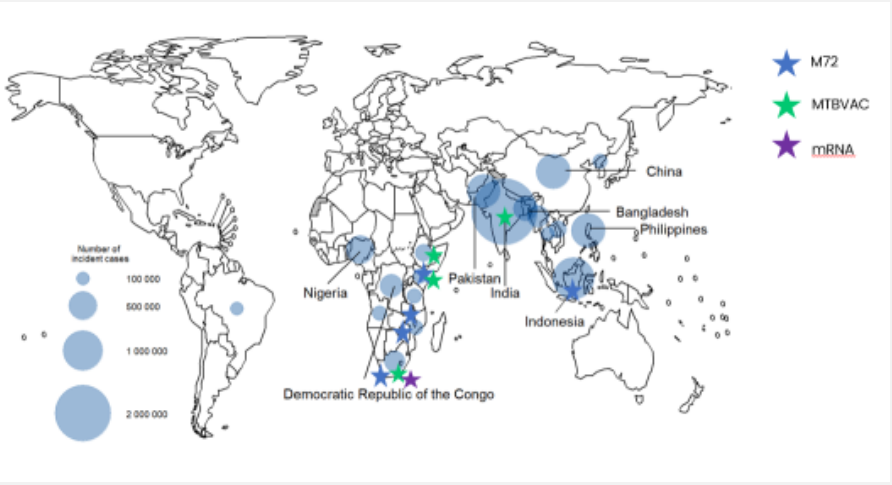
Norbert Ndjeka[a,1], Priashni Subrayen[b,*,1], Willem A. Hanekom[c], Waasila Jassat[a,d], Angelique Kany Kany Luabeya[e,f], Nkateko Mkhondo[g], Rudzani Muloiwa[h], Phumeza Tisile[i], Thobani Ntshiqa[b], Jody Boffa[b], Birgitte Giersing[j]

With thanks

- Bavesh Kana, Wits Faculty of Health Sciences, Wits University
- Kate O’Brien, IVB, WHO HQ
- Gitte Giersing, TB division, WHO HQ

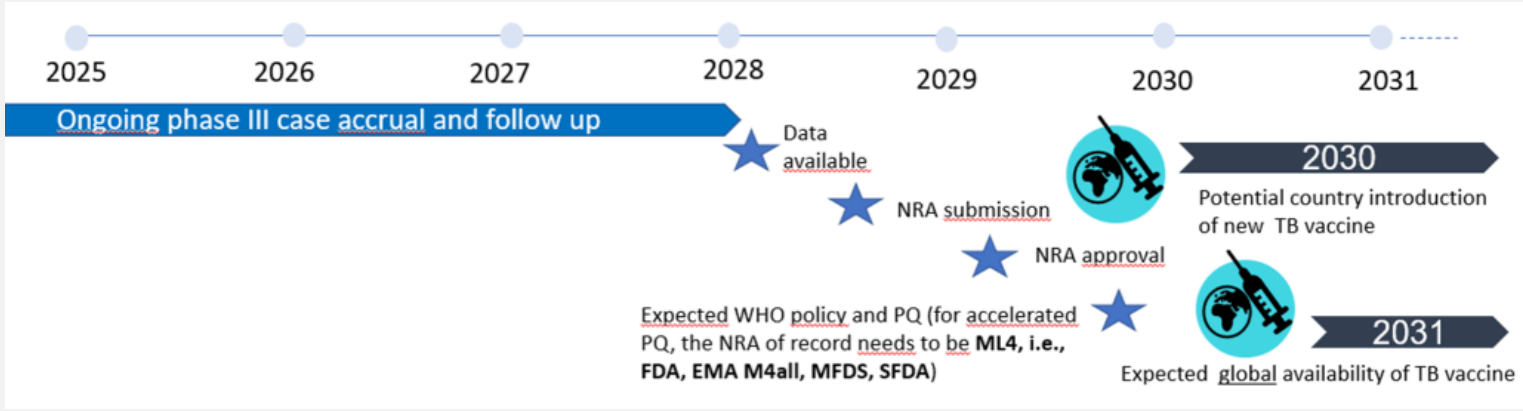
Accelerating new Tuberculosis vaccine development Potential availability 2031

Estimated number of incident TB cases in 2023, for countries with at least 100,000 incident cases



Incidence: 10.8 million;
1.25 million deaths in 2023

Timeline



2031: Expected global availability of TB Vaccine

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