



7TH GLOBAL FORUM
ON TB VACCINES

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Rio de Janeiro, Brazil

Driving innovation from discovery to access

Preparing for TB vaccine approval, scale up and implementation – experience in South Africa

Prof Norbert Ndjeka

Chief Director, TB Control and Management (South Africa)

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Outline

Why we need a TB Vaccine

Political and strategic commitment

National Policy Pathway for TB Vaccines

Harmonization with Regional Regulators

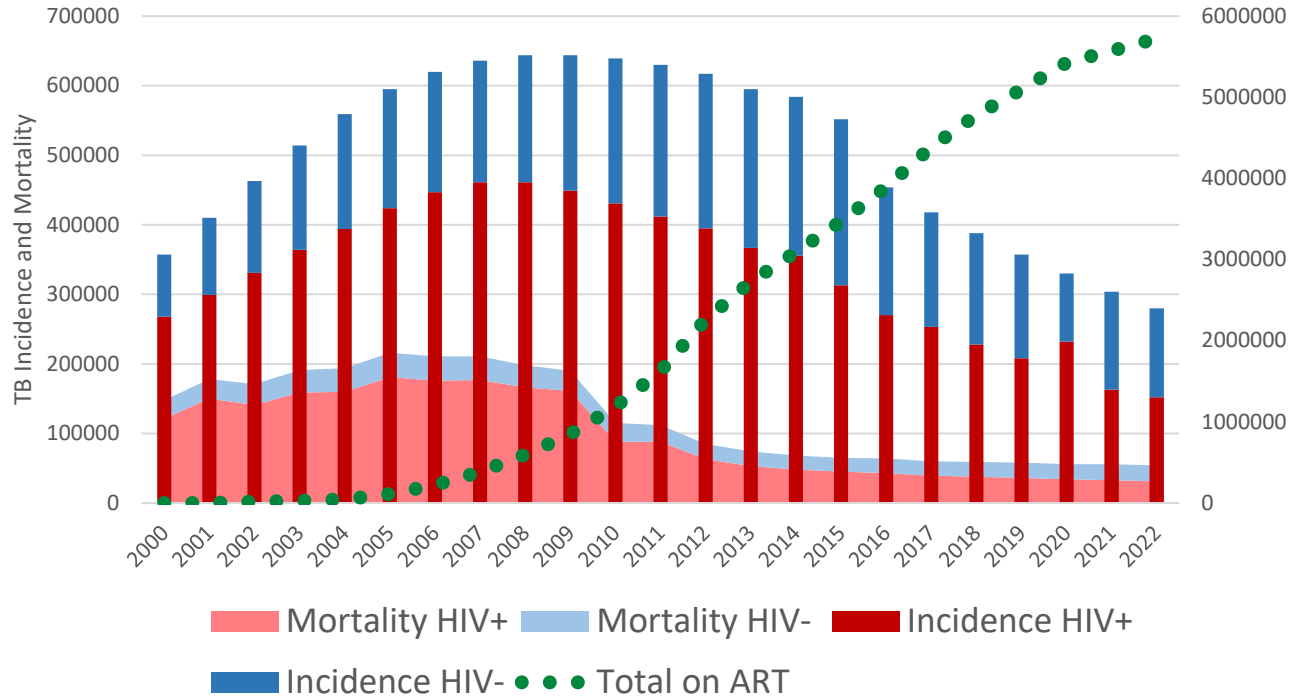
Regional Manufacturing Investments

Defining TB Vaccine Implementation Strategy

Delivery Systems in Place

The need for a TB Vaccine

TB Burden in South Africa



1. [WHO TB Global report 2023](#), Thembisa v 4.7 (ART)

End TB Targets for South Africa

South Africa (End TB Targets)	2022 (current status)	2025 (End TB milestone)	2030 (End TB milestone)	2035 (End TB target)
Percentage reduction in TB incidence rate from 2015 baseline	54%	50%	80%	90%
TB incidence targets (per 100,000 population)	468	508	198	99
Percentage reduction in TB mortality from 2015 baseline	17%	75%	90%	95%
TB mortality targets SA	54,000	16,000	6,400	3,200
% Households experiencing catastrophic costs	56%	0%	0%	0%

- Estimated 280k incident TB cases in SA in 2022
- Incidence has reduced significantly (>50%) since 2015, but remains very high (468 /100k pop)
- Reductions greater amongst PLHIV than HIV-uninfected
- Mortality remains high & stagnant for past several years

- Incidence has already reached 2025 End TB target
- Mortality far from 2025 target
- Unacceptably high levels of households experiencing catastrophic costs



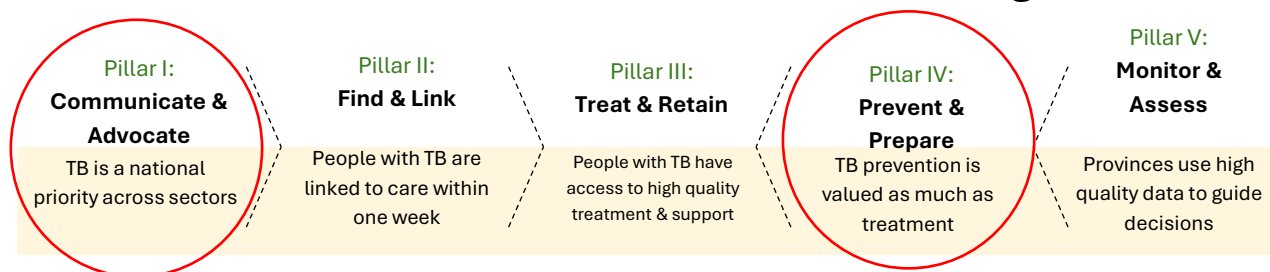
Political and strategic commitment

National TB Strategic Plan 2023-2028, details TB vaccine readiness activities

- Develop detailed procurement plans to secure a timely and sustainable supply of vaccines, partnering with vaccine manufacturers and suppliers to negotiate procurement agreements and ensure a steady supply.
- Securing financial commitments from public and private sectors to fund vaccine procurement and distribution.
- Coordinating with logistics providers to ensure efficient vaccine storage, transportation, and distribution across the country.



Vaccine-related activities in South Africa's TB Strategic Plan



Objective 1.1: Improve internal and external TB communication

Activity: Develop a strategy to combat misinformation to reduce vaccine and treatment hesitancy

Objective 4.3: Prepare for the arrival of more effective TB vaccines

Activity: Engage with national and global programmes to monitor vaccine candidates

Activity: Prepare a vaccine implementation plan

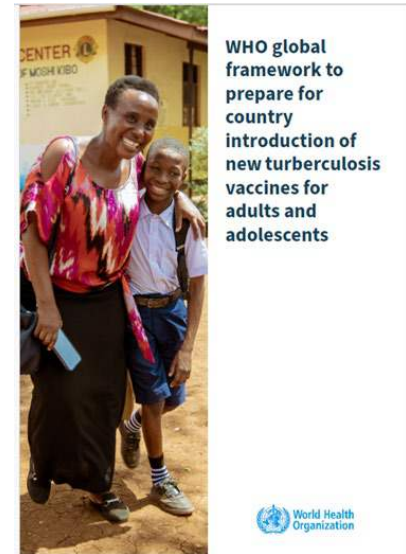
Minister is member of TB Vaccine Accelerator Council



National Policy Pathway for TB Vaccines

National Advisory Group on Immunization (NAGI), TB Vaccines Working Group

- **Terms of reference**
 - Scope of activities guided by WHO Framework
 - Quarterly meetings
 - Members drawn from NTP, EPI, TB Think Tank, academics, researchers, community advocacy groups
- **Data needs and evidence for NAGI/NTP policy recommendations; and regulatory approval and licensing**
 - Role of South Africa's NAGI in identifying critical evidence needs and policy gaps before TB vaccine introduction.
- **Pre-implementation research, evidence gaps for national policy**
 - Efficacy in younger adolescents, other key populations (PLHIV, older adults, people with diabetes, malnutrition)
 - Assess feasibility of deploying vaccines through various delivery models



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	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • Implementation strategy defined (for priority populations; via a mix of 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; change of practice) • Sustainable financing strategy in place (e.g., national health sector strategy; external donors; private payers) 	<ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Appropriate presentations • Funded implementation research 	Regulatory and Policy <ul style="list-style-type: none"> • 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 	Supply and manufacturing <ul style="list-style-type: none"> • Affordable vaccines • Sufficient supply • Sufficient and diversified manufacturing capacity • Access, IP and procurement agreements 	Financing and political engagement <ul style="list-style-type: none"> • 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) 	

Harmonization with Regional Regulators

- SADC
 - End TB Committee (govt officials, CSOs)
 - Regulators forum: SAHPRA and regional regulatory authorities
- AFRO
 - African Medicines Agency (AMA) and African Vaccine Regulatory Forum (AVAREF) to streamline regulatory requirements for TB vaccines across the continent.
- Harmonized Data Requirements: Alignment of data needs to meet the requirements of various national regulatory authorities, ensuring quicker approvals and availability across multiple African nations.



Joint reviews

Providing a standardized regulatory and ethics process involving authorities from multiple countries to increase efficiency of Clinical Trial Application review process



Harmonisation

Working toward standardisation of the regulatory processes to enhance efficiency and improve transparency



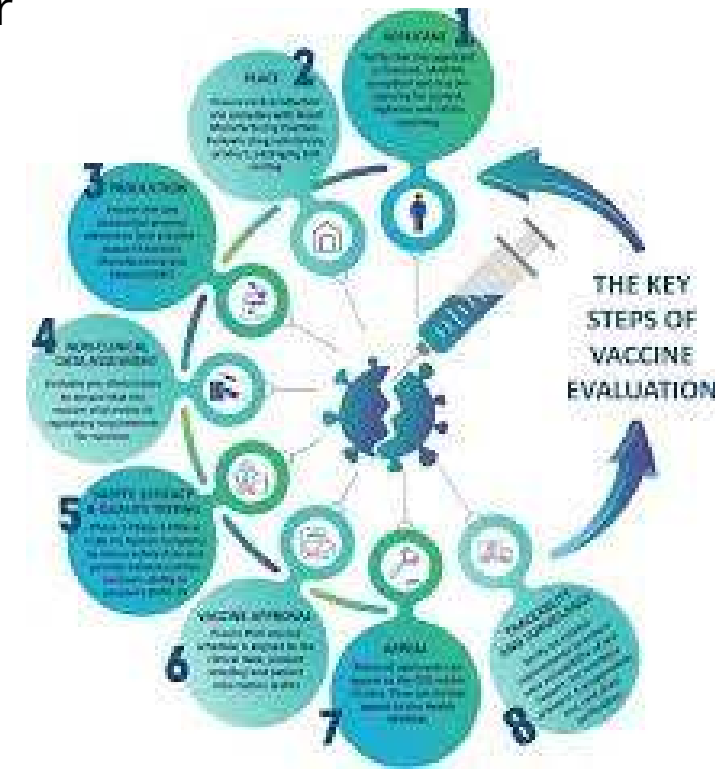
Collaboration

Ensuring ethics committees and regulatory authorities of all member states collaborate and develop strong relationships



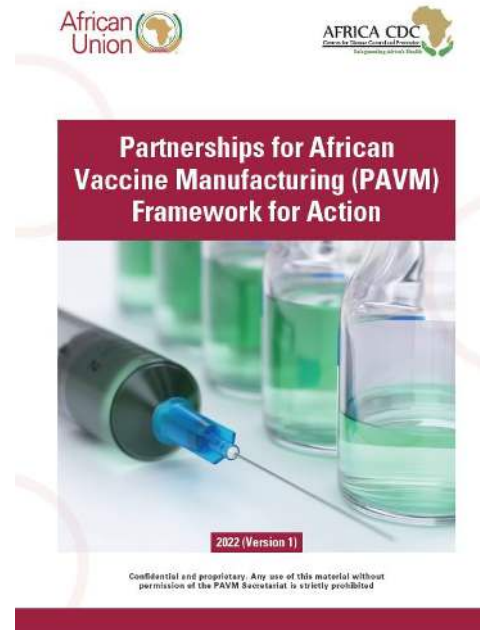
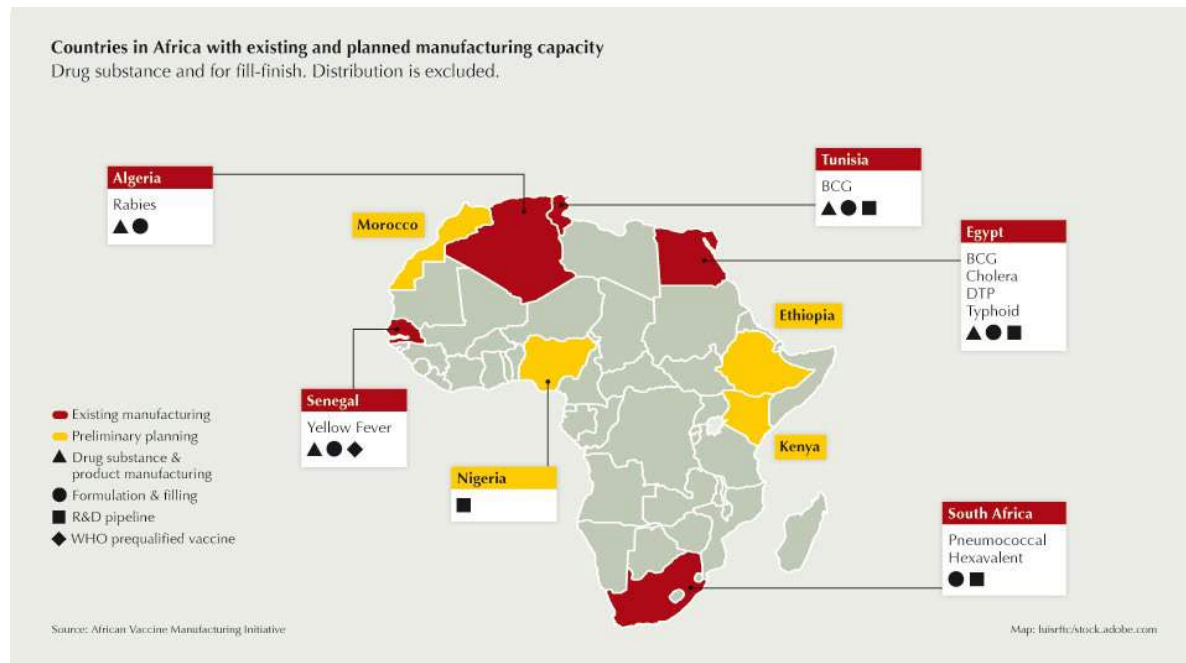
Support

Providing support to all member states with a focus on building institutional / technical capacity to meet demand in Africa



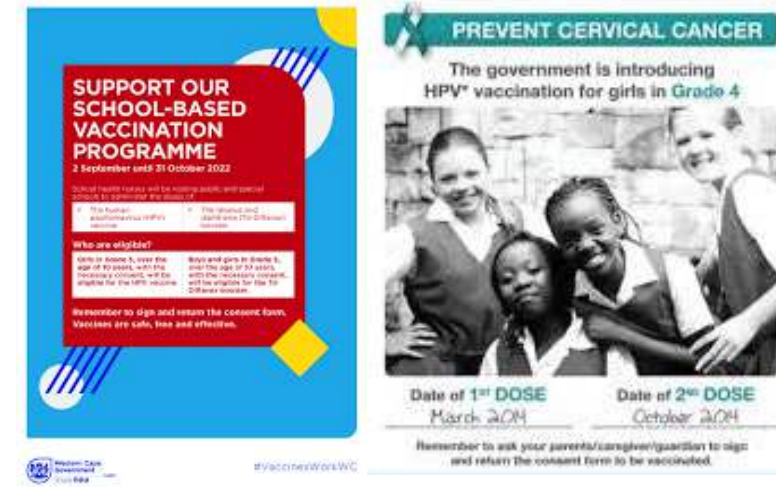
Regional Manufacturing Investments

- Facilitate dialogue between manufacturers, regulators and procurement partners
- Assess role of local and regional manufacturers
- Expand capacity of regional hubs for vaccine production and partnerships with international vaccine developers.
- Secure pricing and volume commitments from manufacturers (Advance market commitments, regional pooled procurement mechanisms)
- Public-Private Partnerships: Government incentives to attract private sector investments, ensuring long-term sustainable vaccine supply.



Defining TB Vaccine Implementation Strategy

- Integrate TB vaccines into the National Immunization Strategy
- Short-, mid- and longer-term strategies to ensure equitable vaccination of all priority populations
- Optimal delivery strategy based on the defined priority population and vaccine characteristics (cold chain, number of doses required)
 - routine immunization, campaign approach
 - school vaccination, PHC services, workplace, TB and HIV programmes
- Draw on experiences with the **COVID-19 and HPV vaccine** rollouts to address adolescents and adults, focusing on tailored delivery mechanisms for priority groups.
- Conduct implementation research/pilot studies to inform vaccine rollout in different contexts/using different strategies
- Consider phased introduction to manage demand for priority populations.
- Engage other govt departments (Education), affected communities, civil society organizations and HCWs



Delivery Systems in Place

• Health System Readiness

- Define and cost TB vaccine delivery
- Assess health system readiness
 - Provincial TB vaccine readiness plans: Assess the number of HCWs needed, training, data monitoring and recording systems, pharmacovigilance, infrastructure, logistics and supply chain requirements
- Address context-specific gaps in implementation and access

• Post-Licensure Surveillance

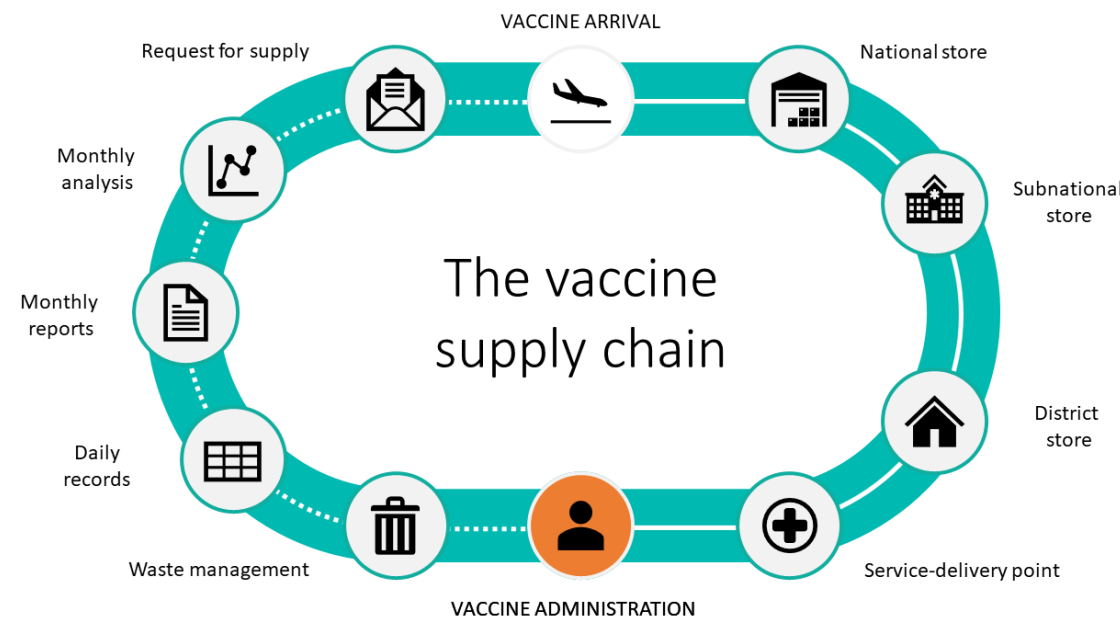
- Collaborate with manufacturers for post-licensure surveillance (pharmacovigilance, post-implementation vaccine effectiveness studies)
- Create risk management plans to address regulatory concerns and maintain public confidence.



Readiness indicators in South Africa's TB Strategic Plan

Objective 4.3 Prepare for the arrival of more effective TB vaccines

Indicator: Number of provinces passing vaccine readiness assessment		
Baseline (2022)	Milestone (2025/26)	Target (2028)
TBD (new metric)	40%	80%



Conclusion

- A TB vaccine is urgently required to address the high burden of TB, HIV and DR-TB.
- It affects the most marginalised and results in catastrophic costs to people affected by TB.
- South Africa has included TB vaccines in strategic and operational planning as a priority.
- Implementation to prevent misinformation starts 2025.
- Collaboration with researchers through NAGI and TB Think Tank.
- NAGI has established a TB vaccine working group., tasked with providing evidence to policy recommendation and guidance on service delivery platforms.
- Opportunities for regional regulatory harmonization in SADC and AFRO.
- Advocacy for financing, regional manufacturing capacity and equitable global supply.
- Vaccine implementation strategy will consider vaccine attributes and defined priority populations, lessons learned from COVID-19 and HPV vaccine programmes.
- Provinces will be supported to conduct health system readiness for vaccine implementation.



ACKNOWLEDGEMENTS

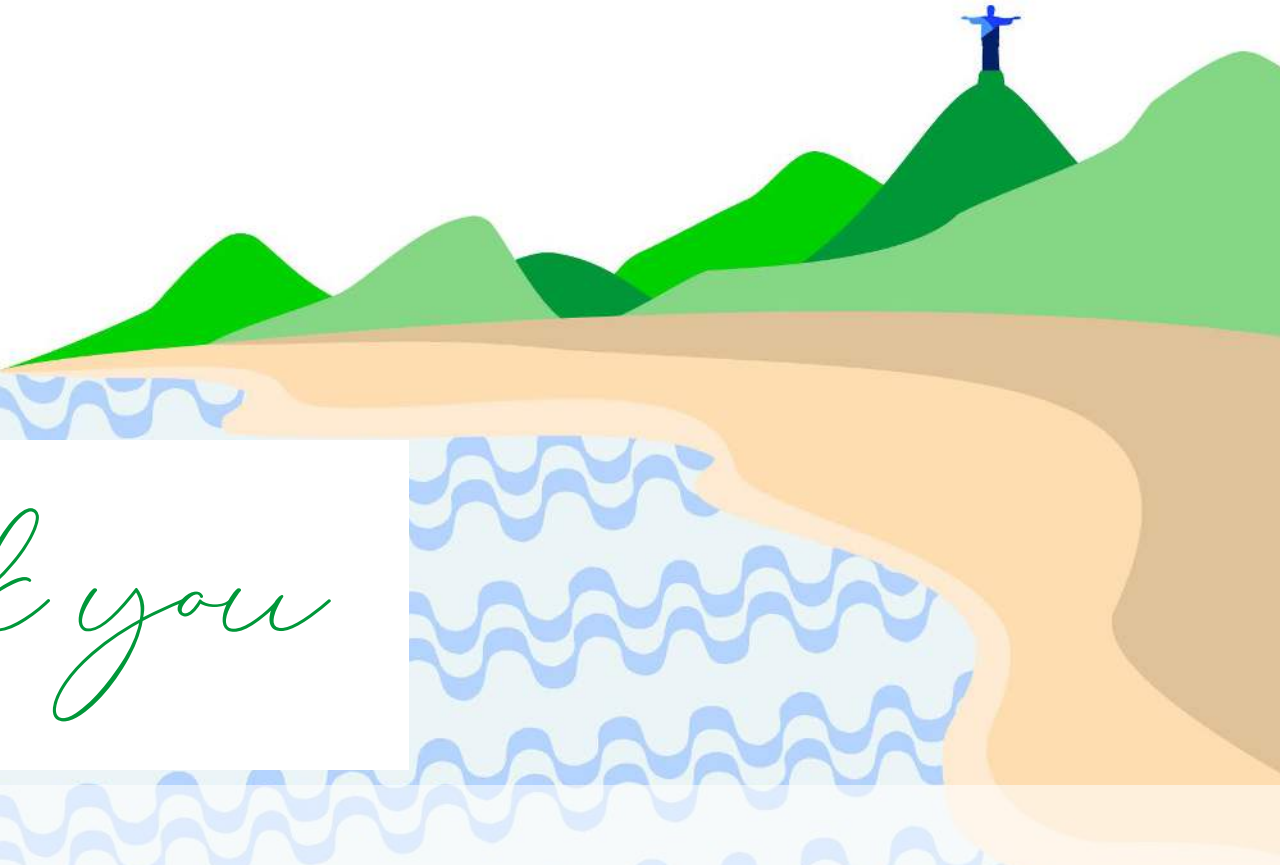
NAGI

TB Think Tank

Provincial TB managers

Jody Boffa

Waasila Jassat



Thank you



An international convening of the

Organized in collaboration with



Translating science into global health impact



MINISTÉRIO DA SAÚDE

