7TH GLOBAL FORUM ON TB VACCINES | 8-10 October 2024 Rio de Janeiro, Brazil

Driving innovation from discovery to access

Ensuring adequate supply to meet demand

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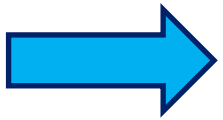
In the lead up to launch, several key enablers critical to ensuring timely supply of vaccines that meet countries' needs

WHO GLOBAL FRAMEWORK FOR COUNTRY INTRODUCTION OF NEW ADOLESCENT AND ADULT TB VACCINES

Informed supply planning & manufacturing scale up is essential

Ensuring affordable, sustainable, and equitable, supply critical



Vision & Purpose

A world free of TB, with zero deaths, disease, and suffering due to TB

Facilitate rapid introduction and scale up of new adult and adolescent TB vaccines

Goals

Available	Accessible	Accepted
Sufficient, sustainable, and timely supply	Equitable delivery aimed at all who could benefit	Policymakers, end-users and health system requirements met

Milestones

Available	Accessible	Accepted
• **Demand assessed** (for short, medium and long term for priority populations; with regard to other interventions) • **Policy, evidence needs, and pathways defined** (e.g., approvals, recommendations, efficacy, and safety data required, specific populations; country testing) • **Procurement plans in place** (e.g., agreements with local and global manufactures, 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; private providers) • **Delivery systems in place** (capacity; infrastructure; supply chains; pharmacovigilance; vaccine efficacy; phase IV studies) • **Sustainable financing strategy in place** (e.g., national health sector strategy, the Global Fund, Gavi, private pay)	• **Value defined** (i.e., at individual and population levels and from perspective of health workers, policy makers, vaccinees; vis-á-vis safety and efficacy) • **Community engaged** (i.e., priority populations, TB survivors, health workers, advocates, policymakers) • **Robust communications strategy in place** (e.g., localized; responsive to community concerns and priorities)

Approach

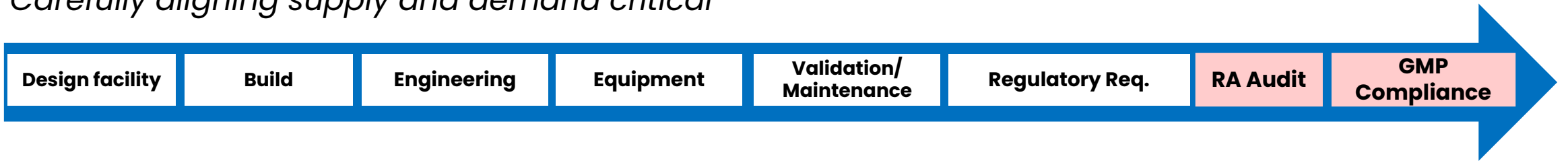
Accelerated, Coordinated, Integrated, People-centred, Equity-driven, Evidence-based

Enablers

Programmatic suitability	Regulatory and Policy	Supply and manufacturing	Financing and political engagement
• Appropriate presentations • Funded implementation research	• Appropriate phase III efficacy trials • Rapid, harmonized regulatory pathways • Licensure in high-burden countries • WHO guidance/recommendation • 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)

Manufacturing scale-up requires considerable lead time and expense

Carefully aligning supply and demand critical



SIGNIFICANT LEAD TIME NEEDED.

✓ To build, start-up and validate a facility could take several years (5+ years).
✓ Tech transfer requires additional time and lot-to-lot consistency clinical studies to support licensure.

HIGH INVESTMENT COSTS

✓ Manufacturing site with capacity 200 M – 300 M doses/year – 50 M USD – 500 M USD[1]
✓ Requires highly specialized work force, administrative & manufacturing overhead, maintenance, revalidation, QMS.
✓ Alignment of the process among multiple facilities needed (Tech-Transfer).

CLEAR MARKET UNDERSTANDING CRITICAL

✓ **Understanding market key to calibrating capacity and ensuring optimal utilization**.
✓ Delivery strategies such as mass campaigns will require extra production effort for a limited period.
- *Gavi VIS projects a 1x catch-up campaign to require 620 mill (16-18 y/o) - 3.6 billion (16-44 y/o) doses*

IMPLICATIONS FOR VACCINE ACCESS

✓ Misalignment between supply capacity and demand has implications on vaccine availability and cost:
- Over-capacity = sustainability risk/increased costs
- Under-capacity = supply shortage

[1] Plotkin S, Robinson JM, Cunningham G, Iqbal R, Larsen S. The complexity and cost of vaccine manufacturing - An overview. Vaccine. 2017 Jul 24;35(33):4064-4071. doi: 10.1016/j.vaccine.2017.06.003. Epub 2017 Jun 21. PMID: 28647170; PMCID: PMC5518734.

Efforts to support market understanding underway

- Stakeholder consultations with national and global leaders have begun to identify key demand scenarios and areas of uncertainty with respect to demand assumptions
- Further validation planned in 2024-2025 to inform demand projections

Jan 2023

Model development

Initial forecast developed (June 2022)

Initial external validation

Pressure test assumptions: GAVI, MMGH, Wellcome Trust, CHAI (Jun 2022 - Jun 2023)

Model comparison

Compared structural and parameter assumptions (Sept - Nov 2023)

Nov 2023

Apr 2024

External consultation to validate assumptions & uncertainties
(Financing bodies, high burden country public sector, civil society, implementers)

Online consultation (Apr 2024)

June 2024

Gavi Board decision

Scenarios in modeling include 14-16 y/o with 1x catch-up campaign

Oct 2024

India expert meeting

To inform India TB vax investment case

Nov 2024- 2025

Further validation of impact per demand scenarios & forecast refinement

Takeaways from Demand Forecasting consultations to date

Target populations and implementation strategies will vary by country, including:

- PLHIV (on ART)
- TPT eligible (household contacts of TB patients)
- Health care workers
- People living in congregate settings e.g. miners, correctional services,
- Those with co-morbidities (diabetes mellitus, smokers, and pregnant women post partum)
- Routine roll out based on EPI or school/university linkage

Vaccine characteristics will be a key driver of uptake:

- Price
- 1 vs 2 doses
- Age group targeted
- Absence of IGRA screening requirements
- Safe for use in people living with HIV

Regional manufacturing approaches prioritized in key settings:

- Country pre-requisites/prioritization of local supply strategy may shape procurement decision

The context of other potential interventions important:

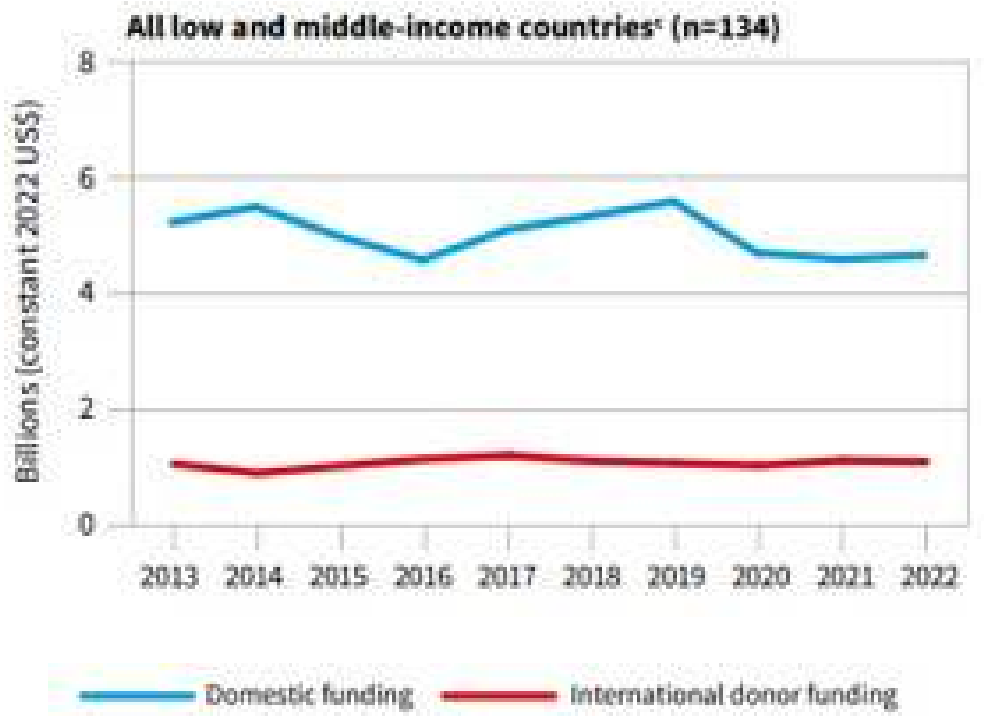
- Need to validate how vaccines will be applied in the context of TPT, BCG-based interventions, and other prevention interventions

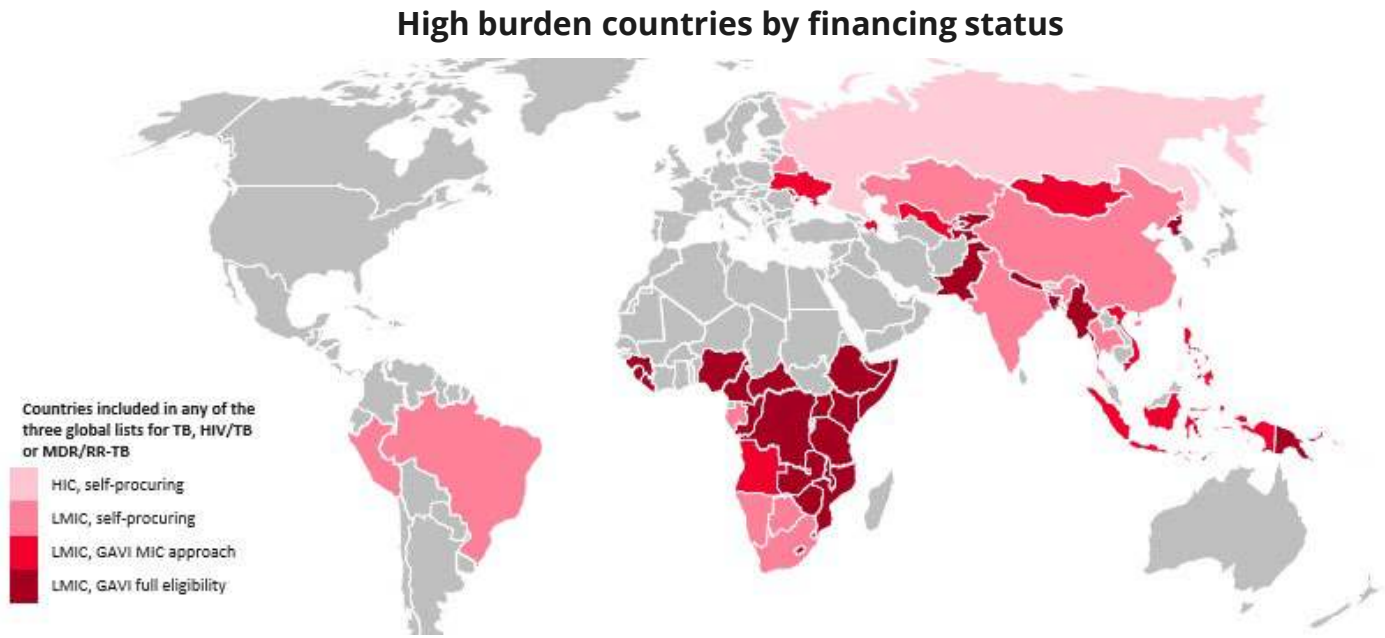
	M72	MTBVAC
TARGET POPULATION	ADULTS, ADOLESCENTS	INFANTS, ADULTS, ADOLESCENTS
PHASE OF DEVELOPMENT	PHASE 3 (ADOLESCENTS / ADULTS)	PHASE 3 (INFANTS) PHASE 2B (ADOLESCENTS/ ADULTS)
DOSE SCHEDULE	2 DOSES	1 DOSE
SAFETY DATA IN PEOPLE LIVIING WITH HIV	YES	YES
SAFETY & IMMUNOGENICITY DATA IN IGRA NEGATIVE POPULATIONS	TES	PLANNED (contingent on funding)
MANUFACTURING PARTNERS/ FOOTPRINT	GSK (UK) OTHER TBD	BIOFABRI (EU) BHARAT (India) FAP & FIOCRUZ (Brazil)
PRICE	TBD	TBD

Middle income countries will drive global demand

Understanding implementation strategies in MICs will be critical

- Most TB occurs in LMIC countries that are not GAVI eligible or are transitioning:
  - 68% of TB is in 8 middle income countries: India (27%), Indonesia (10%), China (7.1%), the Philippines (7.0%), Pakistan (5.7%), Nigeria (4.5%), Bangladesh (3.6%), S Africa (2.6%)
- Most financing for the TB response is domestic.
  - Understanding MIC implementation plans key to understanding overall likely demand
  - For self financing countries, price and associated implementation costs will have strong impact on scale of introduction





1. Global tuberculosis report 2023: https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2023 ;

Conclusions

- Understanding likely demand for a TB vaccine in parallel with clinical development is key to avoiding delays in manufacturing scale up
- Misalignment of supply and demand can lead to vaccine shortages, introduction delays, high vaccine costs, and manufacturing sustainability challenges
- Vaccine implementation scenarios will differ depending on vaccine financing (domestic vs Gavi), target populations (adults, adolescents, infants), priority use cases across national contexts, and vaccine product profiles
- Coordinated efforts to refine demand understanding at the national and global levels are needed
- Planning for ample, affordable, equitable, and sustainable supply to meet demand critical for impact. Mobilizing the resources and political will to make this a reality is imperative

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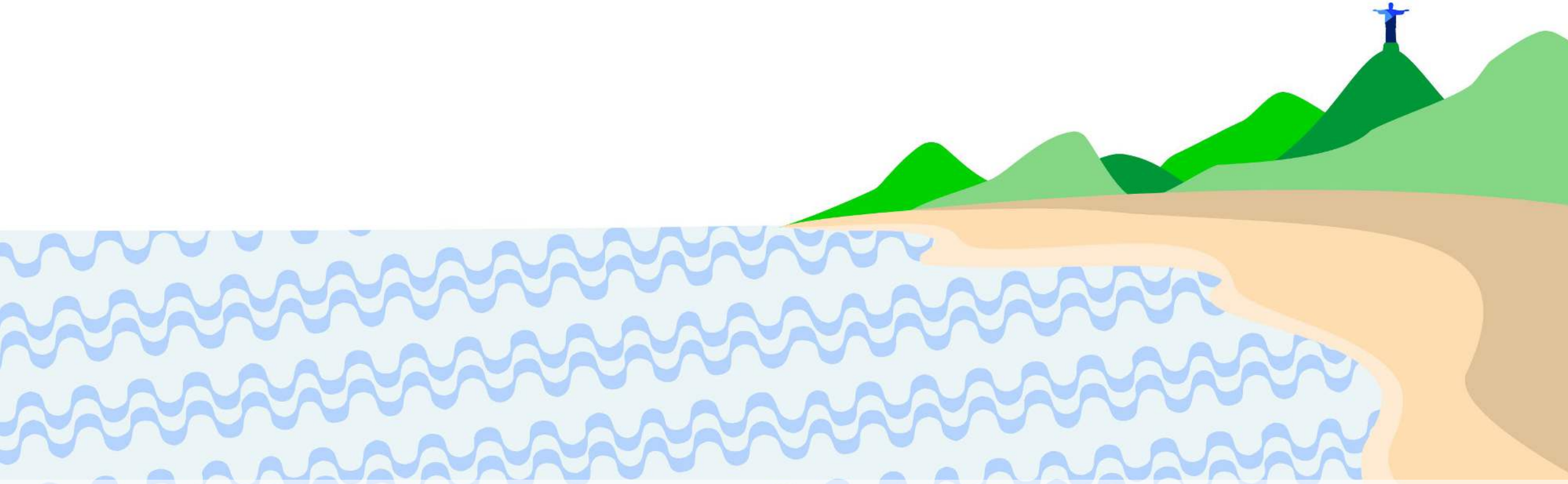
And many other generous individuals and partners around the world

As of July 2024



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8-10 October 2024
Rio de Janeiro, Brazil

Driving innovation from discovery to access

An international convening of the

Stop TB Partnership
WORKING GROUP ON NEW TB VACCINES

Organized in collaboration with

iavi
Translating science into global health impact

TBVI
TuBerculosis Vaccine Initiative

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