Country-synthesis: Critical Pathway Analysis for New TB Diagnostics Adoption

Asia

Overview: Asia

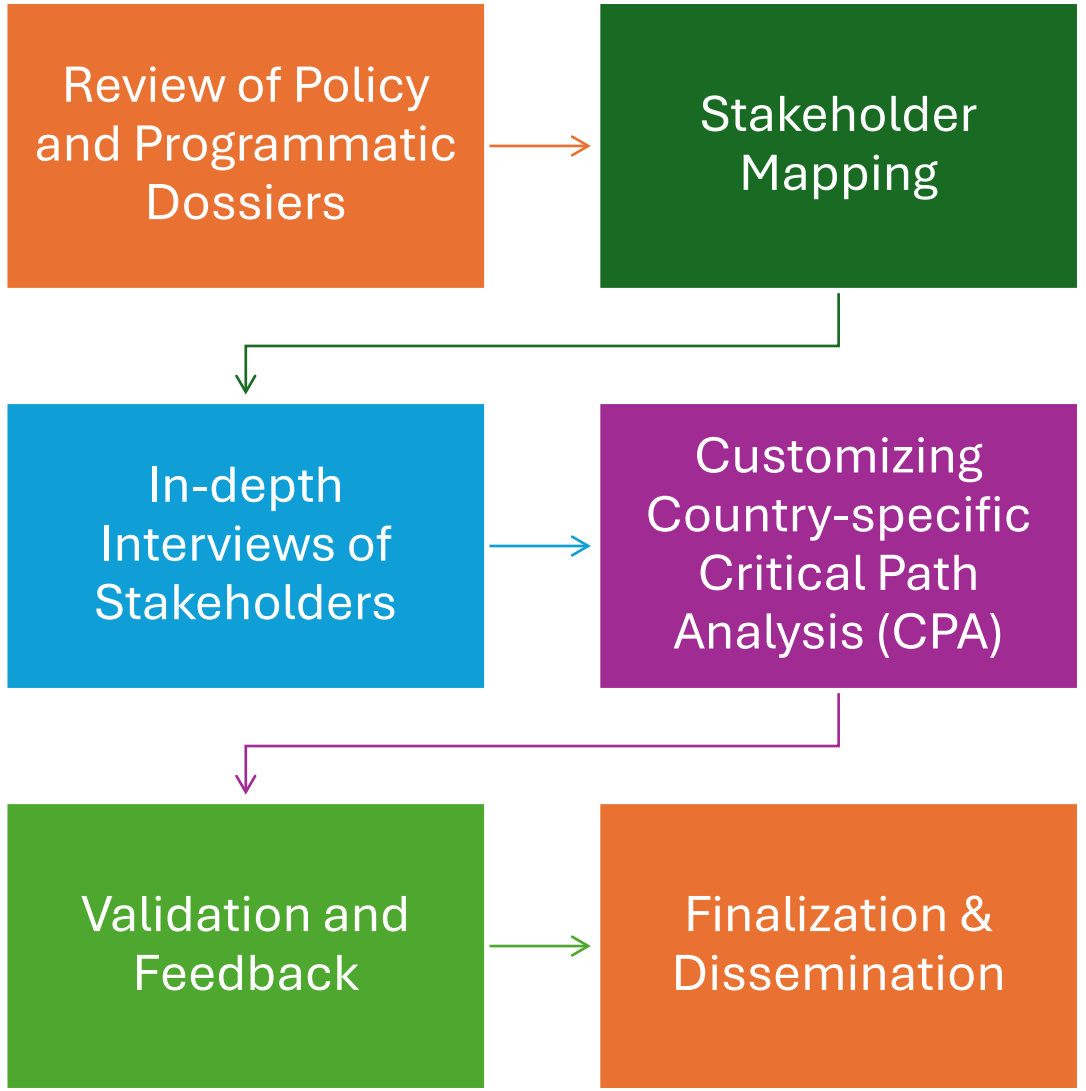
Participating countries:

India, Pakistan, Bangladesh, Indonesia

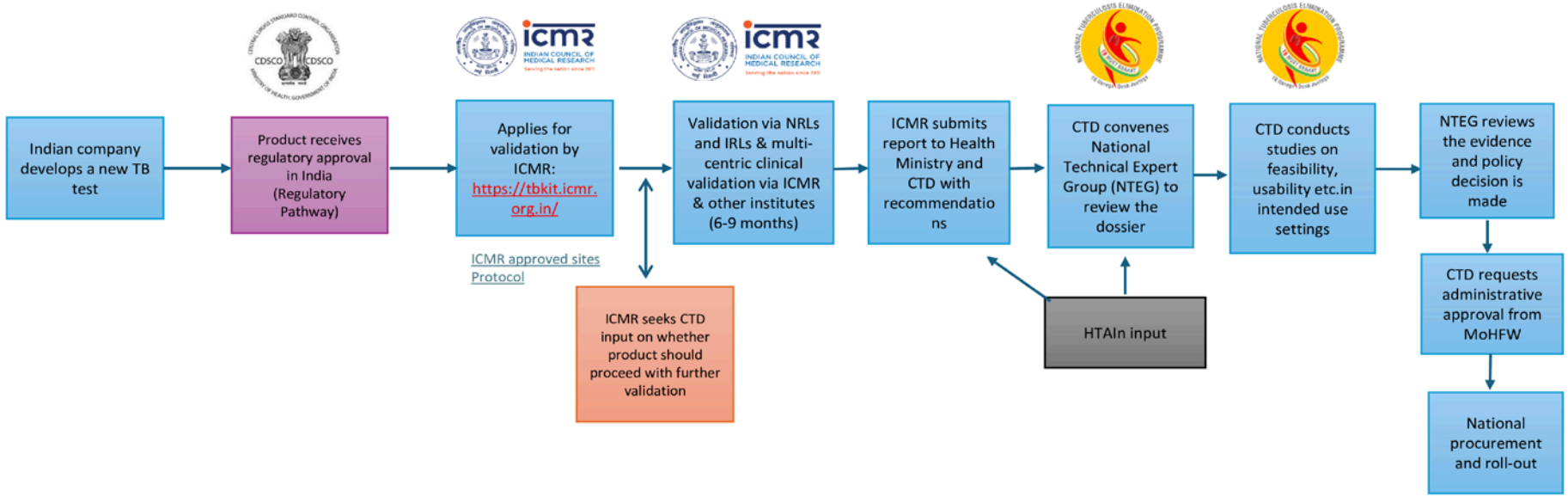
Countries and partners

Country	Partner/grantee	Leads
Indonesia	UNPAD	Ari Probandari, Bachti Alisjahbana
India	FIND	Mikashmi Kohli
Bangladesh	CHRFBD/McGill	Senjuti Saha, Shahidul Islam
Pakistan	AKU/McGill	Sadia Shakoor

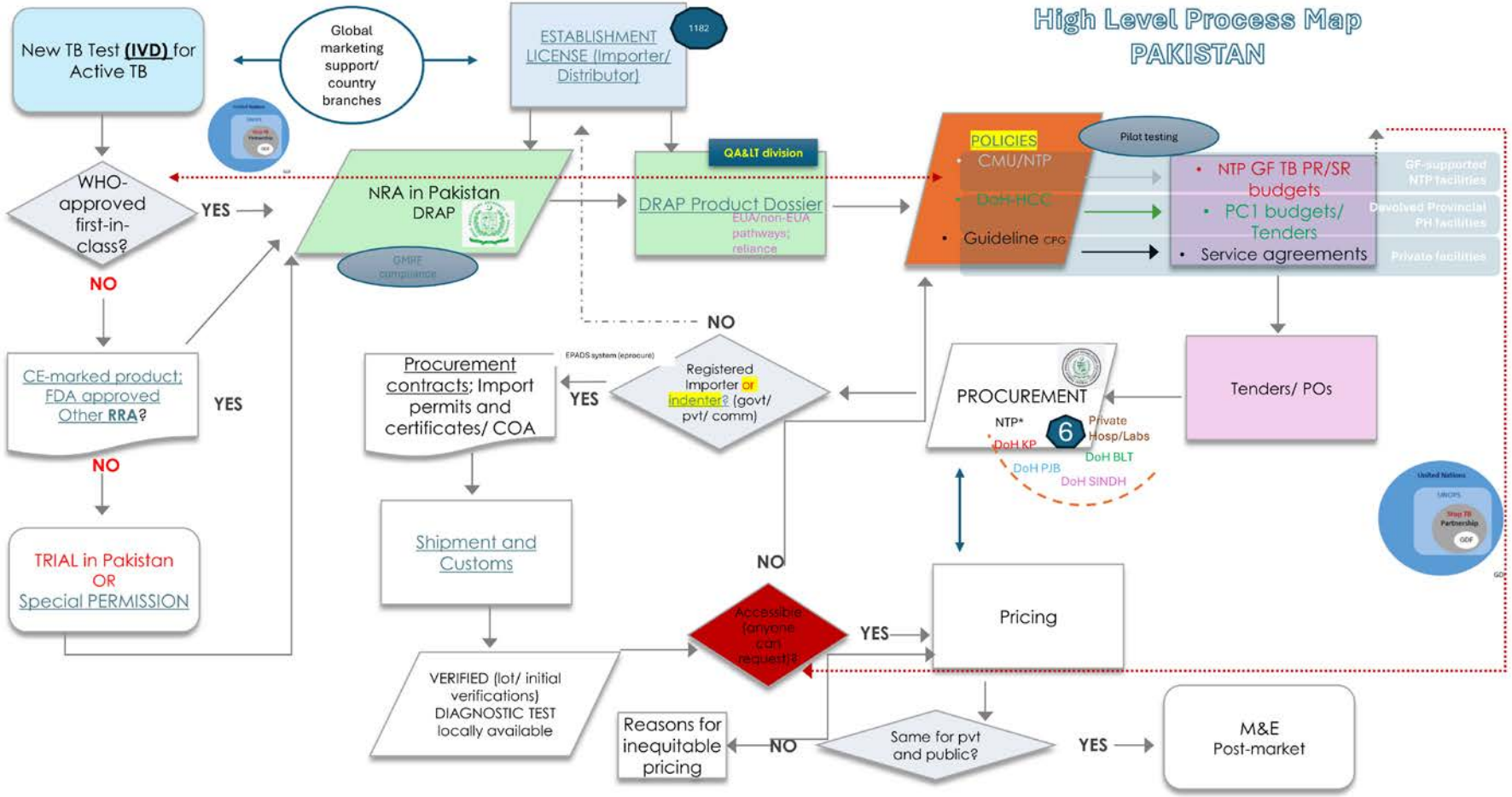
Methodology



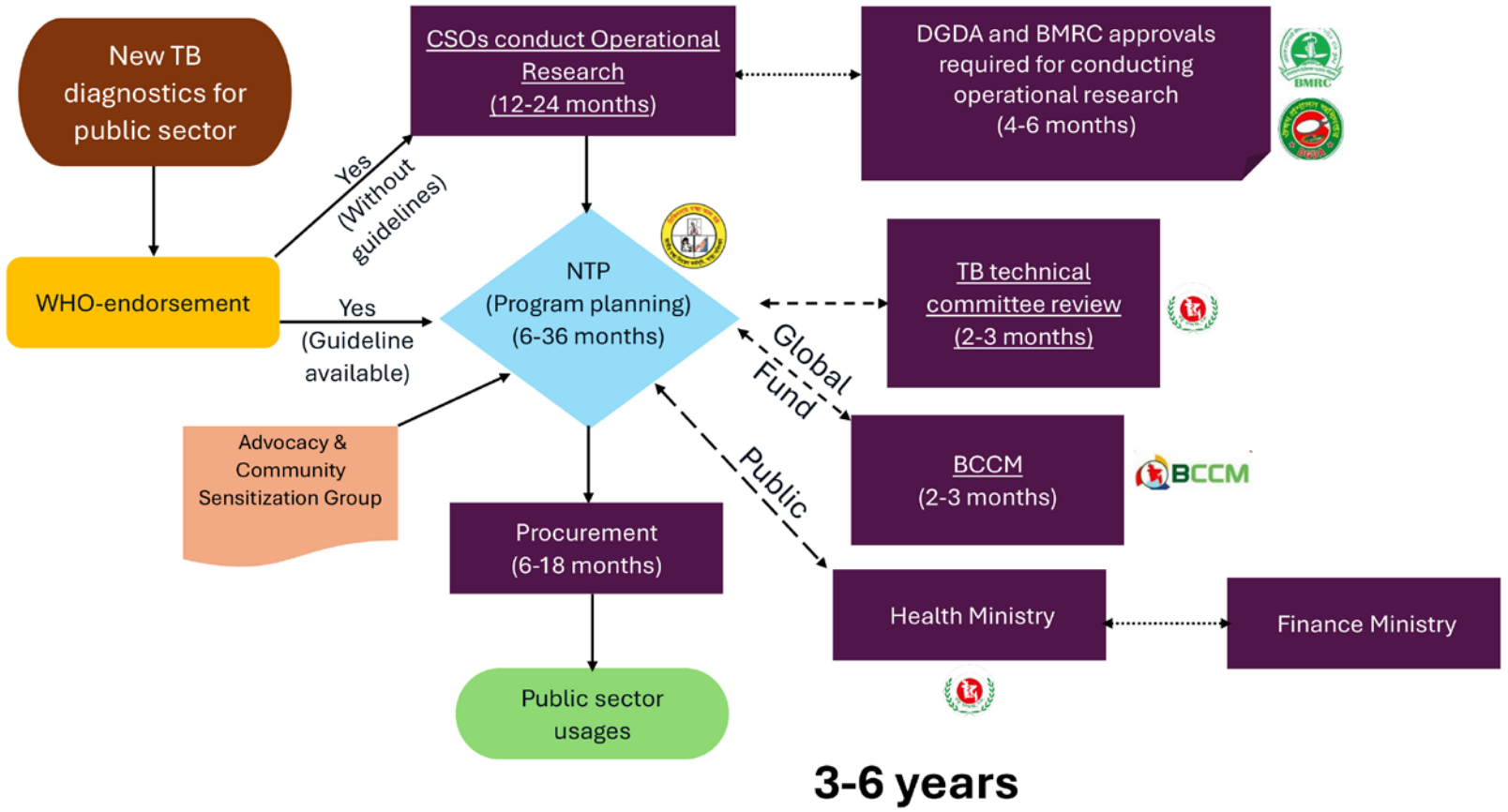
India: Critical path for public sector



Pakistan: Critical path for public sector



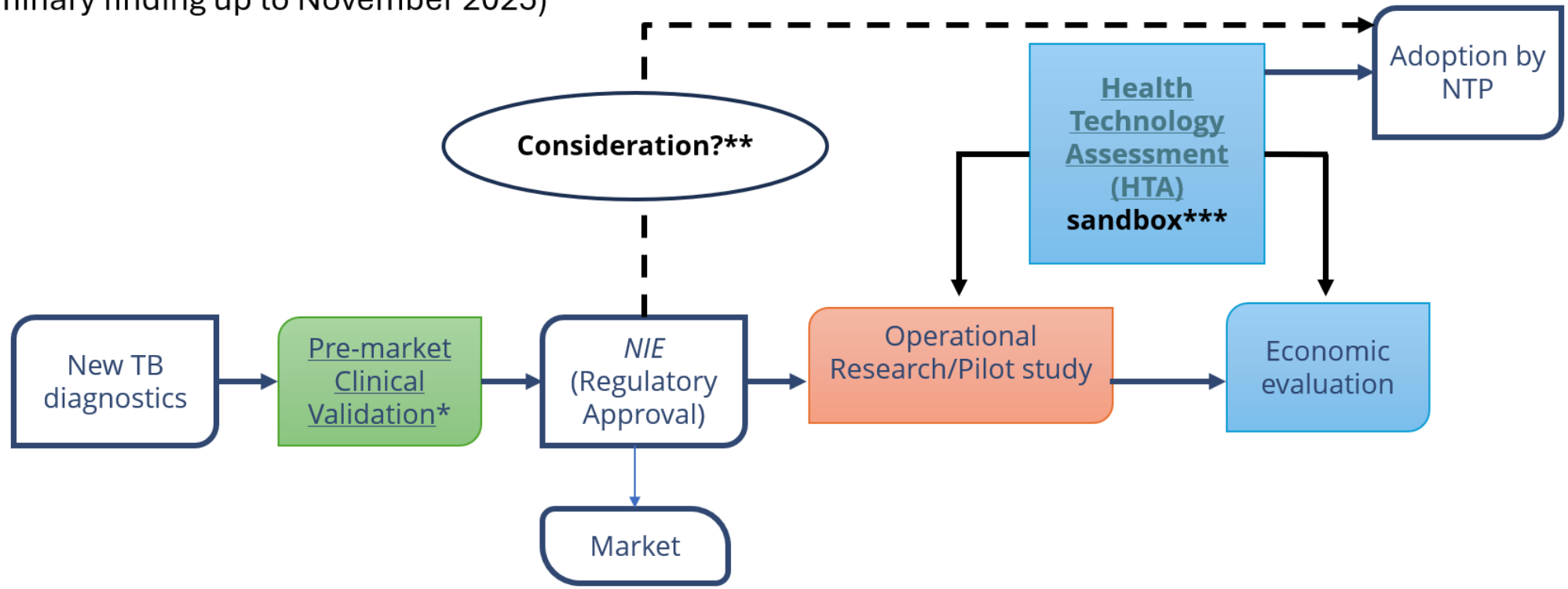
Bangladesh: Critical path for public sector



Indonesia: Critical path for public sector

Co-creation: Pathway for Tuberculosis Diagnostics

(preliminary finding up to November 2025)



*) The guideline of pre-market clinical validation was finalized (September 2025). Consideration of fast-track adoption without HTA is now being discussed, and can be the urgency of new diagnostic test for TB

**) Perceived urgency by the MoH

***) The HTA Sandbox is still general, and HTA for diagnostic tests has not been incorporated in the "new framework" of HTA (sandbox)

Indicators for cross-country analyses

- **Product origin**
- **Regulatory requirements (Global)**
- **Regulatory requirements (national)**
- **Enablers**
- **Barriers**
- **Timelines**

Product origin

	Asia			
	India	**Pakistan**	**Bangladesh**	**Indonesia**
What technologies are majorly used in country for TB detection				
Do countries use imported technologies for TB detection?	Yes (but major focus on in-country technologies)	Yes	Yes	Yes
Do countries use technologies made in country for TB detection?	Yes	No	No	Yes

Regulatory requirements (Global)

	Asia			
	India	**Pakistan**	**Bangladesh**	**Indonesia**
1. Reliance/ collaborative pathways				
WHO recommendation/PQ	Not strictly required; only for GF procurement	Not strictly required, preferred by CMU/ NTP	Not strictly required; but mandatory for GF procurement	Not strictly required, but facilitator
Past TB test adopted without WHO Recommendation/PQ?	Yes	No	No	No
Recognized Regulatory Authorities (Other than WHO)	EU, FDA, Japan	USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland and United Kingdom.	FDA, CE or ISO certifications	No

Regulatory requirements (national)

	Asia			
	India	**Pakistan**	**Bangladesh**	**Indonesia**
1.Regulatory stakeholders				
National Regulatory Authority (NRA)	CDSCO	DRAP	DGDA	Farmalkes
WHO GBT	Level 3 (Vaccines)	Level 2	Level 2	Level 3 (Vaccines)
National approval mechanism via	ICMR	Common Management Unit (CMU)/ NTP	TB/ Technical committee/NTP	Farmalkes and NTP

Regulatory requirements (national)

	Asia			
	India	**Pakistan**	**Bangladesh**	**Indonesia**
3.Registration approval duration in public sector				
Regular review	~20 months	~12 months	6-12 months	4-6 months
4.Marketing authorization validity				
Initial	5 years	5 years	5 years	5 years
Renewable	Yes	Yes	Class B, C & D: 5 Years Class A: Lifetime	Yes
5.Uptake in national policy				
Local validation	Clinical performance evaluation and test validation	Clinical performance evaluation and test validation	Operational Research	Operational/pilot study, Health Technology Assessment (HTA) and Sandbox
Key stakeholders	CDSCO, ICMR	CMU/ NTP	CSO	BKPK, Farmalkes, NTP

Key Enablers

Asia			
India	**Pakistan**	**Bangladesh**	**Indonesia**
❖ **Standardized protocols** for independent evaluation ❖ **Easy online access** to ICMR portal ❖ Multiple **innovation hubs and technology incubators** ❖ **Transparency** of validation results ❖ Regular **ICMR-CDSCO workshops.** ❖ **Various governmental initiatives for new manufacturers**	❖ **GF-WHO** partnership and recommendation ❖ **Political patronage** ❖ Use DNO to locate sites for new platforms **not covered by Xpert.**	❖ **Recommendation** from WHO, FDA, CE or ISO certifications ❖ **Supporting data** from other high-burden countries.	❖ Revision of **standard protocol for** independent evaluation ❖ **GF-WHO** partnership and recommendation ❖ **MoH Policy/Program** (e.g., Integration of PlusLife tongue swab into Free Health Checkup Program).

Key Roadblocks

Asia			
India	**Pakistan**	**Bangladesh**	**Indonesia**
❖ NTEG meeting frequency unclear ❖ CDSCO protocol is **not easily available and understood** ❖ No assessment standards for **AI-based tools** ❖ New process of HTA where protocols and assessment is **unclear on usability, cost effectiveness and feasibility.**	❖ Manufacturers' reluctance to **invest in certifications** ❖ **Political instability** affecting CMU/ NTP leadership and retention ❖ **Limited program capacity** for DNO/ change/ expansions ❖ DRAP application **not entirely online.**	❖ **Dependant** on donor support ❖ Substantially **long duration** to incorporate into National TB Program ❖ Limited role of **private sectors** in TB diagnosis.	❖ The new guideline of premarket clinical validation and HTA sandbox is **still under development** ❖ **Possibly delay** of pre-market clinical validation due to limited number of standardized labs.

Approval timelines for historical products: Xpert MTB/RIF

Country	WHO Recommendation Year	Policy Uptake Year (NTP)	Time to National Adoption
India	2010	2012	~2 years
Pakistan	2010	2012 (pilot), national ~2013	~2–3 years
Bangladesh	2010	~2012	~2 years
Indonesia	2010	2012	~2 years

Approval timelines for historical products: Truenat

Country	WHO Recommendation Year	Policy Uptake Year (NTP)	Time to National Adoption
India	2020	2020 (NTEP inclusion)	Immediate (0 years)
Pakistan	2020	Not registered	N/A
Bangladesh	2020	2022	2 years
Indonesia	2020	2022	2 years

Recommendations

NRAs

- **Transparent and streamlined** evaluation protocols & result sharing
- **Enhance engagement** with national regulators and manufacturers to align policies and support WHO-PQ product uptake
- Advocate for **strong political commitment** and **resource mobilization** to scale up TB diagnostics

Global stakeholders (GF, WHO, donors)

- **Expedited and synchronized** regulatory pathways for new technologies
- Pathway for in-country manufacturers to **access global markets**
- **Harmonized mechanisms** for various regulatory agencies- national and global
- **Support** development, pilot implementation, and capacity-building for new TB diagnostics through training and education on implementation, maintenance, and troubleshooting.

Manufacturers

- Ensure **complete documentation** for dossier review and **actively engage** with NTP/MoH at early stage
- Regularly **aware of national and international** quality and evidence standards- TPPs, TSS, national checklists
- Reaching out to **in-country incubators** for handholding and supporting early technologies

Thank you!