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Critical Path Analysis for New TB diagnostics in Kenya

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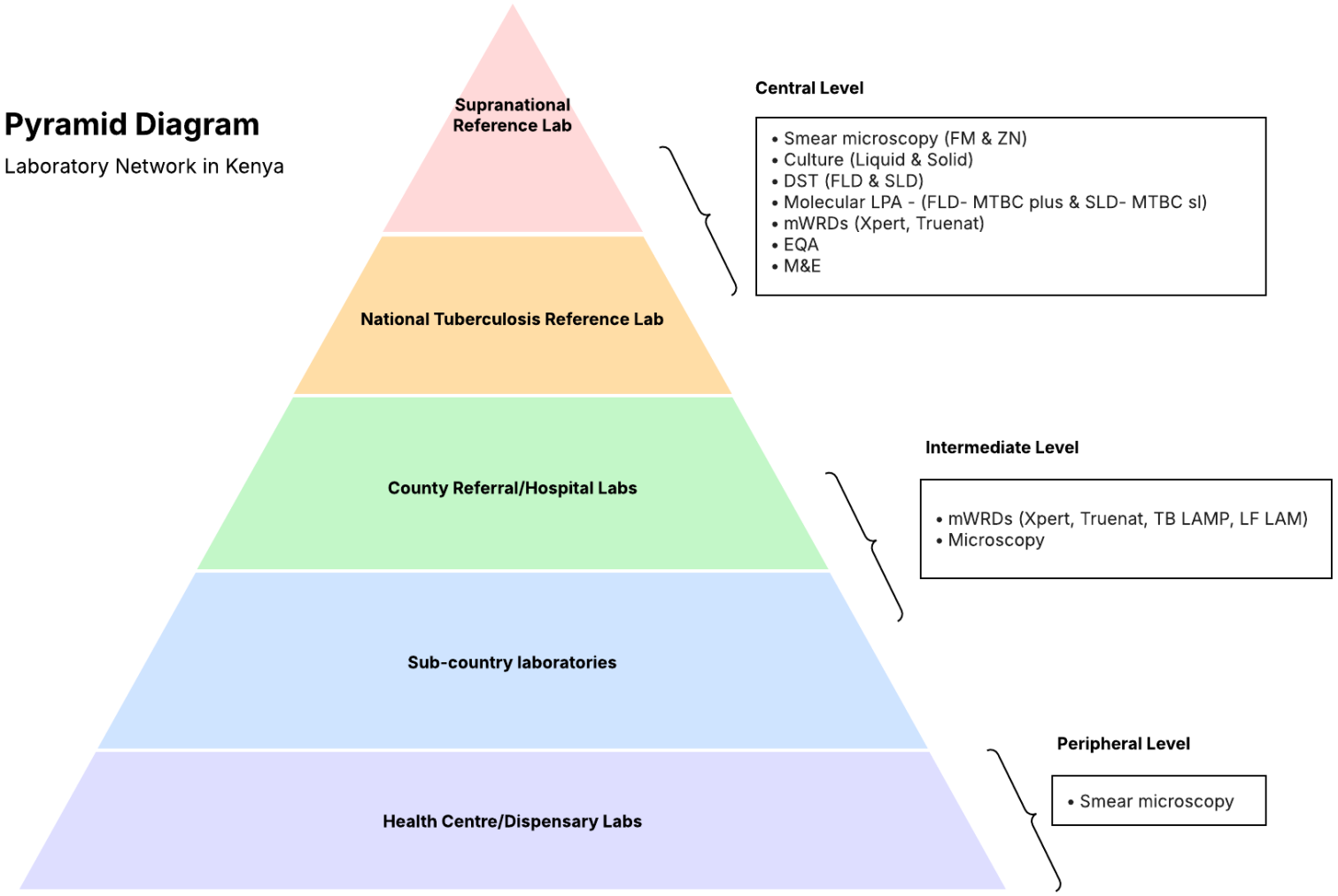
July 2025

Country context: epidemiological profile

Population	55 million
Total TB incidence , 2023:	223 per 100 000 (124 000)
MDR/RR-TB incidence, 2023:	2.2 per 100 000 (1200)
Notified cases of TB, 2023:	94 653
% tested with a WRD:	**54 %**
WB classification:	LMIC
TB funding, 2023:	9.7% domestic **90% international** (Global Fund, USAID, PEPFAR etc.)

Country context: laboratory network



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Key findings
Regulatory processes & uptake into national policy

Regulatory considerations (global /regional)

1. Reliance/ collaborative pathways	
Recognized Regulatory Authorities	GHTF* (Classification rules) WHO PQ recommendation
Regional harmonization	▪ East African Community Medicines Regulatory Harmonization (EAC-MRH) ▪ Regional Centres of Regulatory Excellence (RCORE) in pharmacovigilance
2. Continental mechanisms	
African Medical Agency (AMA) ratification	**Yes –** ratification documents deposited 16th July 2023
Party to Africa Medical Device Forum (AMDF) -TCs	**Yes** [Chair – Paulyne Wairimu PPB]
Africa CDC Diagnostic advisory committee (DAC) member	**Yes**

* Global harmonization task force founding countries: Australia, Canada, EU, Japan, US

Regulatory requirements (national)

1.Regulatory stakeholders	
NRA	PPB WHO GTB ML2*
2.Application for registration (public and private sectors)	
Guiding documents	▪ *Pharmacy and Poisons Act (CAP 244)* ▪ *Guidelines on Reliance Mechanisms for Marketing Authorisation of Health Products and Technologies in Kenya (January 2025)*
Online access to guidelines	**Yes**
Application portal	**Yes**
Language	English
Applicant	Local representative
License	Required
Expedited review pathways	▪ *Full evaluation* ▪ *Abridged evaluation* ▪ *Expedited evaluation*

* WHO global benchmarking tool maturity level 2 indicative of a regulatory system that is evolving and partially functional, but not yet fully stable or integrated.

Regulatory requirements (national)

3.Registration approval timeline	
Regular review	6-12 months
Collaborative registration (EAC-MRH)	~90–120 days (3–4 months) (Assessment timeline)
Expedited review	up to 7 months (received approval from two reference regulatory authorities)
Abridged review	up to 4 months (has obtained WHO PQ)
4.Marketing authorization validity	
Initial	5 years
Renewable ?	yes
5.Authorization of importation	
Conformity assessment	Required, and must submit certificates, test reports, Declaration of Conformity ISO 13485
Other	Proof of pre-market approval or registration from an RRA
Temporary import mechanism	unclear

Uptake into national policy

5.Uptake in national policy	
Local validation	Yes – Committee of Experts (CoE): This committee reviews the algorithms and tools for new diagnostics, engages end users, and ratifies the recommendations before they are approved at the TB health sector working group. Kenya Medical Research Institute (KEMRI)
Guiding documents	Guidelines on Reliance Mechanisms for Marketing Authorisation of Health Products and Technologies in Kenya (January 2025)
Key stakeholders	1. Ministry of Health (MoH) 2. County Governments 3. Committee of Experts (CoE) 4. Donors and Implementing Partners 5. Regulatory Agencies 6. Medical Boards

Barriers/enablers for regulatory approval and adoption into policy

Regulatory approval & adoption into policy	
Enablers	▪ WHO PQ not required for regulatory approval, although is an enabler for expedited review. ▪ Completeness of documents submitted to PRIMS is an enabler for quicker processing. ▪ Established processes post-regulatory approval for inclusion of tests in national policy ▪ NTP already thinking about use of POC tests at primary care levels.
Barriers	▪ Post-market surveillance is required. It can be resource intensive and may pose additional challenges for manufacturers. ▪ Capacity of PPB – have reported requiring more capacity building and skills on IVDs. ▪ WHO PQ required for adoption into national policy. ▪ Operational buy-in to involving lay testers

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Key findings

Procurement and supply chain

Procurement and supply chain considerations

Procurement and Supply Chain	
Guiding documents	***Public Procurement and Asset Disposal Regulations 2020,*** *Regulation 71 (head of the user department must submit a requisition to the head of the procurement function with supporting documentation, including feasibility studies)*
Estimated timelines	*Approval of the procurement application should take a maximum of* ***30 days*** *from filing. The procurement process in total can take* ***6-9 months*** *including the 30 days aforementioned. Steps include:* ▪ *2-3 weeks for initial request and Treasury verification* ▪ *2-3 weeks for quotation or tender process* ▪ *1 month for contract negotiations and legal review* ▪ *2 weeks for payment processing* ▪ *Additional time for pre-shipment documentation, tax exemption, and shipping.* *The entire process can stretch up to* ***9 months****, depending on available resources, complexity of the contract, and coordination between different entities like KEMSA, Treasury, and manufacturers.*

Procurement and supply chain considerations

Procurement and Supply Chain	
Estimated volumes	***Urine-LAM***. *There are approximately 1.4 million people on HIV care and treatment, with approximately 280,000 people (20%) likely requiring TB testing. For overall TB testing, Kenya aims to conduct 1.9 million tests annually, with a current breakdown of 60% for GeneXpert, 30% for TrueNAT, and 10% for LAM tests. Based on this, an initial volume of 28,000 test kits may be made.* ***Swab-based molecular tests***. *4-5 tests per day can be done across 900 facilities, however this would depend on availability of resource and patient sensitisation.*

Barriers/enablers for procurement and supply chain

Procurement & supply chain	
Enablers	▪ Commitment of external funders to fund novel TB diagnostics in country would be an enabler for adoption. ▪ Relatively quick procurement processes.
Barriers	▪ Length of procurement is dependent upon available resources, complexity of the contract, and coordination between different entities like KEMSA, Treasury, and manufacturers. ▪ Funding constraints due to geopolitical factors and shortages of external funding

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Key findings

Use case(s) and implementation

Proposed use cases

Expected use case for next generation near point of care portable oral swab based rapid molecular tests and level of the health system appropriate for their deployment	▪ *Active case finding* ▪ *Symptomatic individuals at primary care network levels can undergo molecular swab testing. (Jeremiah Ogoro, NTP, 5th May 2025)*
Expected use case for next generation LF LAM (irrespective of HIV status) and level of the health system appropriate for their deployment	▪ *Active case finding* ▪ *Urine LAM can be used at the primary care network levels during intensive active case finding. (Jeremiah Ogoro, NTP, 5th May 2025)*

Considerations about implementation and scale up

Early adoption and roll out: health systems & implementation needs	
Training required	*Three types of training are necessary:* *a) Training of Trainers* *b) Training of technical users i.e. laboratory scientists, technicians, and technologists* *c) Training of lay testers i.e. community health promoters/workers*
Network improvement/optimization and M&E	
Enablers	*1. Development of collaborations with manufacturers to develop sustainable in-country connectivity solutions.* *2. The country has experience with DNOs/DNAs being conducted every two years.*
Barriers	*Both the DNOs and connectivity solutions above were introduced by USAID-funded programmes. Given restrictions on USAID funding, it is currently unclear who will finance TB diagnostics DNOs and connectivity solutions.*

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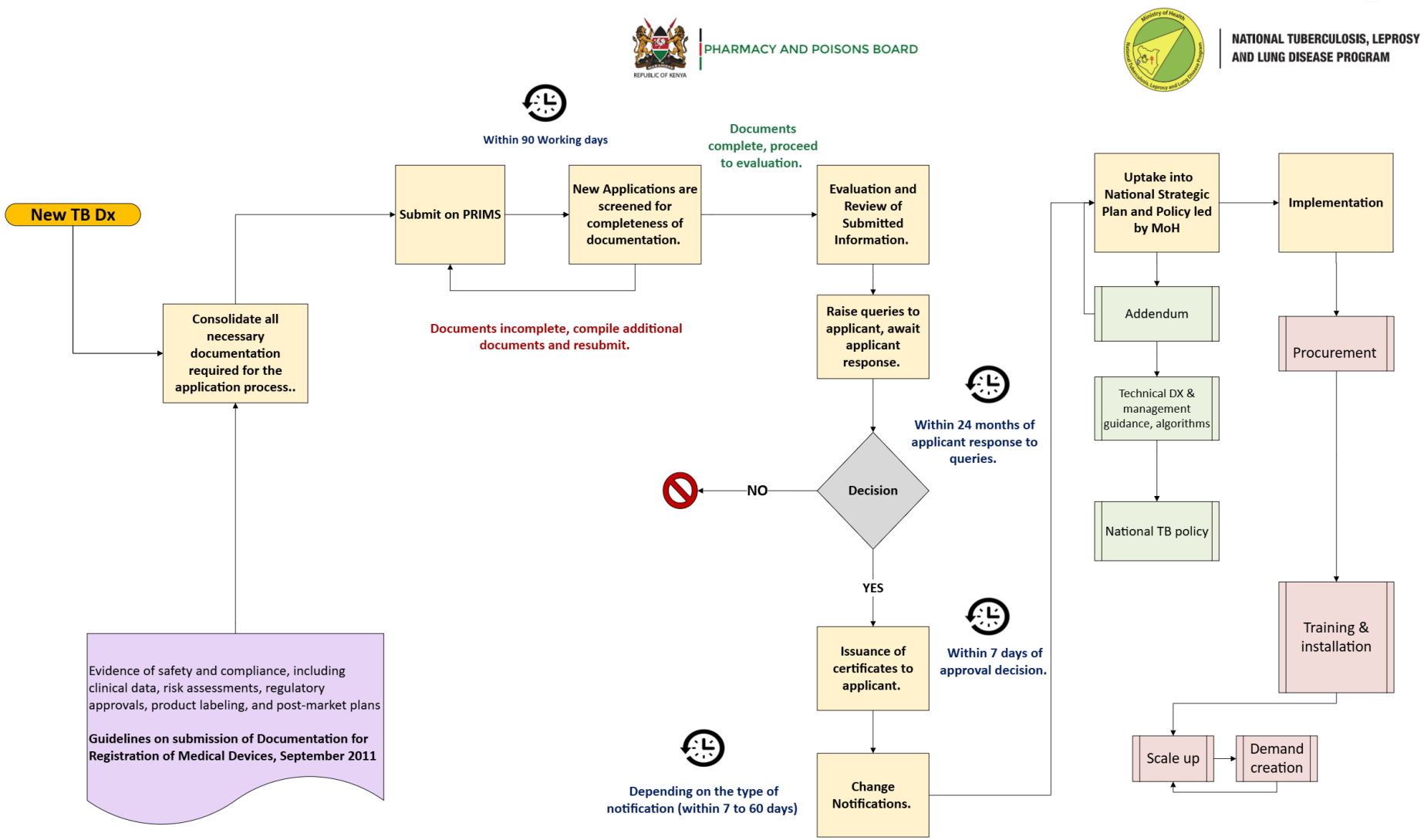
Country CPA roadmaps

New TB diagnostic test introduction in the public and private sector



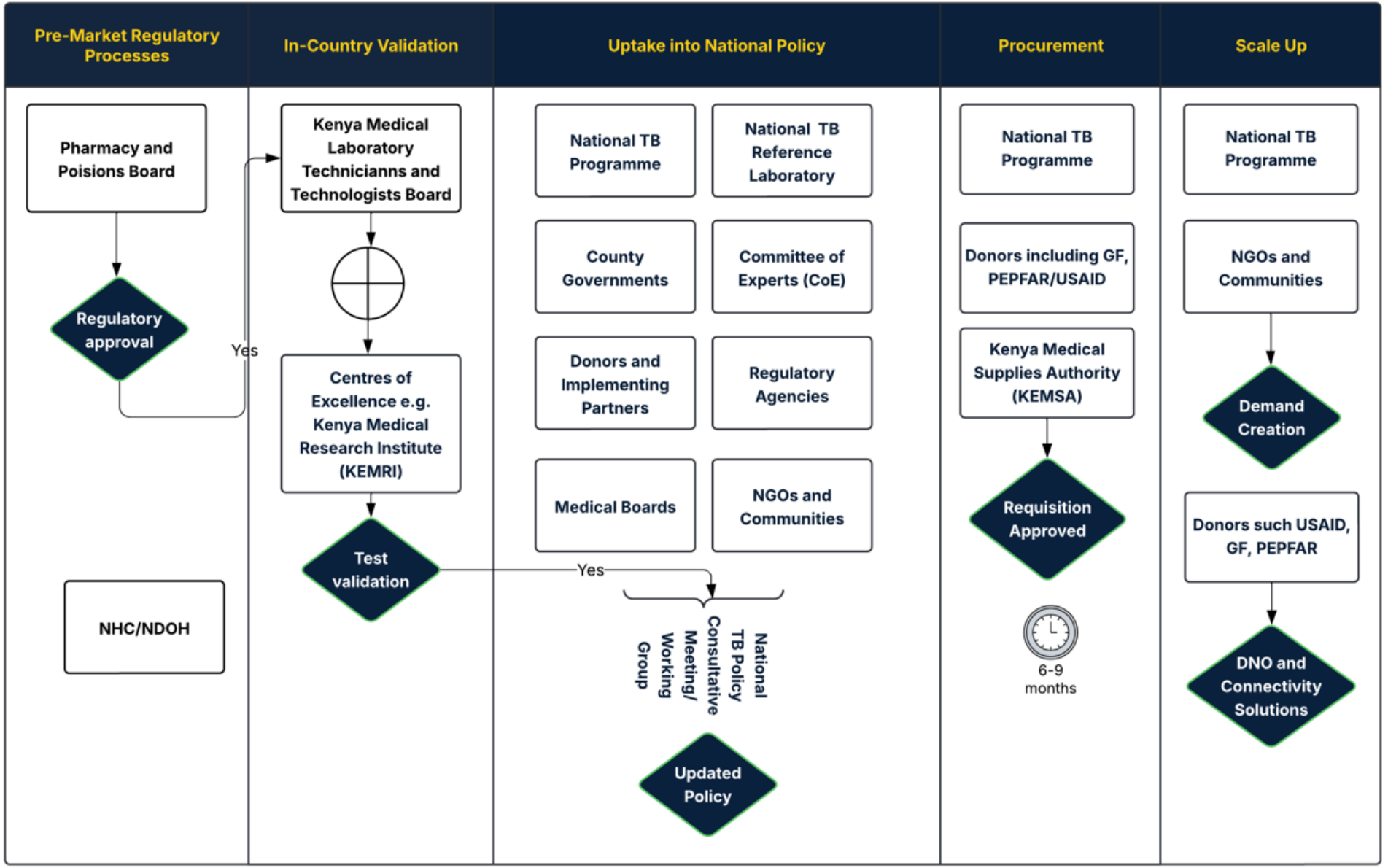
Estimated Duration: 6–9 Months

1. **Initial Request & Treasury Verification**
   - 2–3 Weeks
2. **Quotation or Tender Process**
   - 2–3 Weeks
3. **Contract Negotiation & Legal Review**
   - 1 Month
4. **Payment Processing**
   - 2 Weeks
5. **Pre-shipment Steps**
   - Tax Exemption, Shipping, Documentation
   - Variable Duration

Timeline may vary based on:

- Resource availability
- Contract complexity
- Coordination (e.g., KEMSA, Treasury, Manufacturers)

Stakeholder map



Historical pathway for GeneXpert and Truenat introduction

FEB 2011 — **WHO Policy Statement issued on Xpert MTB/RIF system**

2011 — **Initial Rollout of GeneXpert Instruments in Kenya**

Under national TB guidelines, primarily for detecting Mycobacterium tuberculosis and rifampicin resistance.

2014 — **Implementation of Connectivity Solutions**

Implementation of GxAlert and GXlims connectivity solutions to automate results transmission (via SMS/email) and monitor GeneXpert network performance.

11 APR 2018 — **PPB Regulatory Approval Issued to Cepheid**

2020 — **Adoption of More Sensitive GeneXpert Assay**

Adoption of GeneXpert Ultra (a more sensitive assay) and Truenat molecular platforms to expand diagnostic coverage, particularly in hard-to-reach areas.

2023 — **Scale up and update/integration of connectivity sys**

Scale-up to 239 GeneXpert instruments nationwide, with ongoing integration of Tibulims—an upgraded connectivity system combining case-based data tracking and inventory management

2020 — **WHO recommendation on Truenat**

SEP 2021 — **PPB Regulatory Approval of Truenat**

DEC 2021 — **KMLTTB Test Validation of Truenat**

Molbio filed application in September 2021

JUN 2022 — **Training Conducted at County Level**

Training sessions were conducted for County Medical Laboratory Coordinators (CMLCs) from all 47 counties on the use of the Truenat assay for TB testing.

JUL 2022 — **First Truenat Machine Introduced**

The first Truenat machine was installed at Navakholo Sub-County Hospital in Kakamega County. This installation marked the beginning of the pilot phase for the Truenat platform in Kenya.

DEC 2022 — **Truenat Expanded to 2 counties**

The adoption of Truenat technology had expanded to two target counties, with over 1,900 patients enrolled across more than 190 health facilities

2023 — **Truenat Deployed in 33 counties**

A total of 38 portable, battery-powered Truenat machines were deployed across 33 counties in Kenya. These machines were particularly beneficial in hard-to-reach areas with unreliable electricity supply.