MATAHARI

Critical Path Analysis of New TB Diagnostics in Africa

Final report

Kenya

July 2025

1. Executive summary

This Critical Path Analysis (CPA) assesses the regulatory, policy, implementation and market-entry steps required to accelerate adoption of next-generation TB diagnostics (e.g., next generation urine LAM, oral/swab molecular tests) in Kenya. In the current global context of stalled progress toward WHO targets for universal access to rapid TB diagnosis, recent innovations in non-sputum based and near-POC molecular tests and shifting donor landscapes, the CPA provides a consolidated roadmap to shorten time to impact and inform manufacturers, funders, regulators and national program leaders.

The CPA has identified the following key enablers:

Regulatory Environment: Kenya benefits from clear regulatory pathways managed by the Pharmacy and Poisons Board (PPB), with the ability to expedite approval for WHO prequalified products. The country's participation in continental regulatory bodies such as the African Medicines Agency (AMA) committees further supports regulatory harmonization efforts.

National Strategic Priorities: The National Strategic Plan (NSP) prioritizes diagnostics for high-risk groups and mentions the expansion of testing using non-sputum samples. These objectives align with the anticipated use cases for novel TB diagnostic tools.

Established Diagnostic Network: Kenya's decentralized laboratory network provides a ready platform for integrating new diagnostic tools, across both the public and private health sectors.

Strong Stakeholder Engagement: The multisectoral involvement of government ministries, county governments, donors, civil society, and community health workers ensures coordinated efforts in policy development, implementation, and demand creation.

Experience with network optimization: Kenya has prior experience with diagnostic network optimization across a range of diseases and digital connectivity solutions, which can be leveraged for accelerating the introduction and scale-up of novel TB diagnostic tools.

Conversely, the following key challenges have been identified:

Lengthy Regulatory Approval Timelines: Without WHO prequalification, regulatory approval can extend up to 2 years, significantly delaying market entry and access to new diagnostics.

Personnel Shortages: A critical shortage of trained laboratory and TB program staff limits capacity to manage new diagnostic tools, impacting timely implementation.

Infrastructure and Connectivity Limitations: Inadequate availability and maintenance of essential hardware, coupled with unreliable internet connectivity at health facilities, hinder real-time data reporting and integration with national health information systems.

Procurement and Funding Constraints: Complex procurement processes can take up to nine months, while heavy dependence on external donor funding amid shifting foreign policy is a major risk for financing procurement, training, and scale-up activities.

Community Awareness and Stakeholder Resistance: Low community awareness, cultural stigma around TB, and resistance towards the involvement of lay testers challenge effective roll-out.

Timelines (indicative)

Global/continental: WHO PQ/GDG processes variable: full PQ 270–350 days, abridged 100–180 days with WHO guidelines development group (GDG) recommendations; AMA/AMRH pilots may take 15–45 days for joint review plus country registration windows but do not currently include TB diagnostics in its scope.

National regulatory: regulatory approval can take up to 2 years but, on average, the regulatory process takes 6-12 months. Abridged or expedited regulatory pathways take between 4-7 months with WHO prequalification, or prior approval by a stringent regulatory authority (SRA), respectively.

Evidence to policy: There is no standard timeline established for the introduction of new TB diagnostics into national policy according to Kenya NTP. Historically 6–12 months were required from WHO recommendation to national policy inclusion for GeneXpert and Truenat platforms.

Pricing and financing decisions: 6-8 months.

Scale-up from pilot to nationwide: ~1-2 years from policy adoption to routine use (health system readiness training and roll out of connectivity solutions).

Based on the above, Kenya CPA informed the following **priority recommendations**

For National TB Program and Regulatory Authorities: Maintain up-to-date regulatory information repositories and leverage regional or stringent regulatory authority recommendations when WHO guidance is unavailable. Increase capacity of regulatory experts and develop clear orientation materials for manufacturers to streamline submissions and approvals.

For WHO and Prequalification Teams: Issue clear, timely guidelines and expedite recommendation processes for novel TB diagnostics to facilitate faster country adoption.

For Donors: Allocate budgets specifically for novel TB diagnostics in country grant planning. Support advocacy, demand creation, and collaboration with test developers to fast-track market entry.

For Test Developers: Ensure completeness of documentation and transparency of pricing. Understand and utilize abridged evaluation routes based on approvals from SRAs. Appoint local authorized representatives to facilitate regulatory engagement.

Conclusion

With a TB incidence of 223 per 100,000 population and only 54% of patients diagnosed using rapid diagnostic tests, coordinated efforts focusing on streamlined regulatory processes, sustainable financing, and community engagement/capacity building to enhance demand creation will be essential to close the diagnostic gap. This Critical pathway analysis offers a comprehensive, actionable framework to accelerate the introduction of innovative, accessible diagnostic tools in Kenya through coordinated efforts involving global, national, and local stakeholders.

2. Acknowledgements and Impressum

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This document outlines the methodology used to collect, collate, and validate publicly available data to define a critical pathway analysis for new TB diagnostic aimed at facilitating the market entrance of tests as diagnostics features in different pipeline reports. This critical pathway analysis provides in-depth understanding and documentation of the following key steps along access to new TB test that will assist countries, donors and manufactures in the selection of high-quality TB diagnostics appropriate for their setting and complement the different ongoing initiatives focused on market shaping and increasing access to TB diagnostics in Low- and Middle-Income Countries (LMIC).

This report was informed by the experience and insights of numerous experts involved in TB diagnostics, regulatory pathways, and product registration at the national level. Our thanks to (listed alphabetically by surname):

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5. Abbreviations

CHW	Community Health Worker
FGD	Focus Group Discussion
HIV	Human Immunodeficiency Virus
IVD	In Vitro Diagnostics
LAM	Lipoarabinomannan, a glycolipid component of the *Mycobacterium tuberculosis* cell wall
NSP	National Strategic Plan for Tuberculosis, Leprosy, and Lung Health 2023-2028
NTP	National TB Programme
POC	Point-of-Care
PPB	Pharmacy and Poisons Board
PQ	Prequalification
TB	Tuberculosis
TPT	TB Preventive Therapy

6. Introduction

A. *Problem description and rationale for undertaking the Critical Path analysis*

Since 2011, highly specific and sensitive rapid molecular tests have transformed the TB diagnostic landscape. Furthermore, during the 2023 UN high level meeting, countries committed to the ambitious goal of having 100% of diagnosed TB cases initially tested with a WRDs (mNAAT and LAM) to overcome the setback in TB case detection caused by the COVID-19 pandemic and to accelerate progress towards the targets of the End TB strategy.[1] However, according to the 2024 WHO Global TB report, progress made in providing access to WRDs is now stalling at 48% globally (54% in the African region) representing a gap of 4.3 million, which is a critical bottleneck to achieve the objectives of the End TB Strategy by 2030.

Critical transitions are needed to overcome this diagnostic gap, notably including shifting from microscopy to molecular testing, expanding access to decentralized, POC NAATs and using non sputum samples such as urine and oral swabs.[2] In line with what is seen with diagnostics in general, the gap is exacerbated at primary health care and community level.[3] Additionally, sputum microscopy has challenges with identifying cases with bacterial loads below 10,000 organisms/mL, common in HIV co-infections, paediatric TB, and early-stage disease.[4] Additionally, sputum microscopy has very low sensitivity in extrapulmonary TB, paediatric TB, and HIV-associated TB.[5] As a result, there are whole communities that are being diagnosed late or not at all.

Recent and upcoming innovations in TB diagnostics can increase access to testing for these populations and bring tests closer to communities. According to the Treatment Action Group's 2024 Pipeline Report, there are several upcoming near point-of-care tests that can be used at primary care centres to diagnose these missing cases. These include 36 new NAAT and 6 next generation LAM tests, with urine LAM tests with a range of specificity (range 78-98%) and sensitivity (68.3-93%), and swab-based molecular tests (many with time to result being <30 minutes). Furthermore, a 2024 modelling study showing that point-of-care tests with reduced sensitivities from 70% for non-sputum tests can achieve comparable or better case detection than the current standard of care in each country.[6]

Based on the above facts, there was a need to assess the regulatory pathway for these tests, potential use cases, approaches to ensuring adoption within national TB guidelines, necessary steps to implementation, among key areas – as a consolidated reference for countries, manufacturers, WHO PQ, regulators, and communities that will be involved in demand creation for these novel TB diagnostics. Understanding the critical path for the newer urine LAM tests and swab-based molecular tests is critical to accelerate market entry, adoption and roll out to expand access to testing at all level of the health system, including at primary health care and community level.

B. Kenya country profile

Kenya is a lower middle-income country according to World Bank income classification categories. According to the African Development Bank, Kenya's economy grew 5.2% in 2023 and is projected to grow 5.4% in 2024 and 5.6% in 2025, driven by services and household consumption.[7]

According to the World Health Organization, Kenya has a TB incidence of 223 (128-338) per 100,000 population incidence, with approximately 54% people diagnosed with a rapid diagnostic at time of diagnosis.[8] Tuberculosis continues to be within the top 10 causes of death in Kenya, with 2,798 people dying from TB in 2023.[9] There continues to be testing gaps in Kenya, with a 2021 article stating that only 47% of notified TB cases have access to Xpert MTB/RIF testing (a rapid molecular diagnostic tool).[10] The following table summarises Kenya's TB 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.)

Figure 1: TB Profile - Kenya (Source: World TB Report 2024)

Kenya's laboratory network is a five-tiered decentralised system (see Figure 2 below) designed to support disease surveillance, diagnostics, outbreak response, and research across the country. The network is coordinated at the national level but extends through regional, county, and sub-county facilities, integrating both public and private laboratories to ensure broad access and rapid response capabilities. According to the National Tuberculosis Reference Laboratory Operational Plan 2023-2028, the decentralized TB diagnostic network constitutes 226 GeneXpert machines facilities (including 37 placed in private facilities), 38 Truenat, 26 TB-LAMP, and 3,159 smear microscopy facilities of which approximately 300 have LF LAM testing capability.[11] Altogether, the network services approximately 10,000 public and private health facilities.[12]

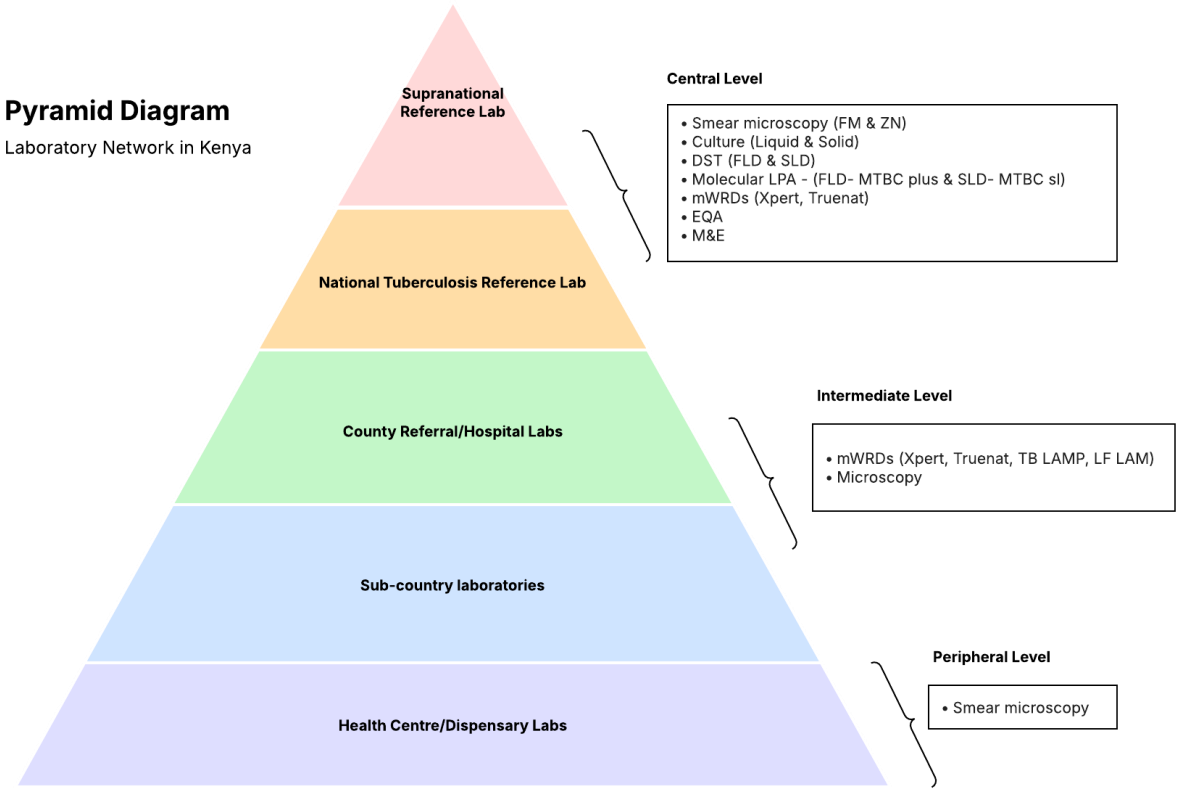


Figure 2: Kenyan Laboratory Network (current as of May 2025)

Work on TB in Kenya is led and coordinated by the **National Tuberculosis Program (NTP)** at the Ministry of Health. The **National TB Reference Laboratory** which is a central hub for TB diagnostics in the country and is mandated to oversee the TB laboratory service delivery in the country. Additionally, the **Pharmacy and Poisons Board** receives applications for approving new diagnostics and medical devices, and in general **has regulatory oversight over all In-Vitro Diagnostics in Kenya**. Other actors include **USAID** who in 2024 stated that they would maintain and sustain support for to optimise sample referral systems for mWRDs and conduct active case finding at the community level,[13] although it is unclear whether these activities are continuing in 2025 pursuant to recent U.S. government priority shifts. Civil society and community groups includes **Stop TB Partnership Kenya** and a network of community health workers that support case finding and linkages into care. Overall, the following parties were involved in the development of the NSP:

- Ministry of Health
- National Treasury
- Ministry of Education
- Ministry of Transport
- Ministry of Interior and Coordination
- County Governments, including County Directors of Health and County/Sub County TB and Leprosy Coordinators
- National Syndemic Disease Control Council (NDSCC)
- National Tuberculosis Reference Laboratory
- AIDS Control Unit
- National AIDS and STIs Control Programme (NASCOP)
- World Health Organization (WHO)
- USAID through Centre for Health Solutions (CHS) TB ARC II
- HealthIT
- Kenya Conference of Catholic Bishops (KCCB)
- Stop TB Partnership
- US Centers for Disease Control and Prevention (CDC)
- Global Fund
- Kenya Coordination Mechanism
- AMREF Health Africa in Kenya
- Kenya Red Cross Society (KRCS)
- Clinton Health Access Initiative (CHAI)
- Kenya AIDS NGOs Consortium (KANCO)
- Respiratory Society of Kenya (ReSOK)
- Central Organization of Trade Unions/Kenya Private Sector Alliance (COTU/KEPSA)
- Kenya Legal and Ethical Issues Network (KELIN)
- Kenyatta University
- TB community representatives

C. *National strategic plan diagnostics priorities*

The country has a National Strategic Plan for Tuberculosis, Leprosy, and Lung Health 2023-2028[14] (hereinafter "NSP") which states that over 48% of incident TB cases in the community are missed, that there is sub-optimal coverage of TB diagnostics including WHO-recommended diagnostics (WRDs), and that only 43% of health facilities where people initially seek care are able to diagnose TB.[15]

The NSP contains numerous strategic objectives, including those focused on strengthening TB services for high-risk groups, defined as:

> *Men, truck drivers; elderly; people in congregate settings i.e., prisons, children's homes and schools, institutions of higher learning, factories and industries, flower farms; military/police barracks, mines, and among alcoholics and people who use drugs (NSP, p. 128)*

Additionally, the NSP also contains strategic objectives focused on cross-border and migrant populations (Strategic Objective 2.1.6, p. 119), which may, due to remote locations, be more suitably offered near point-of-care (POC) or point-of care tests.

Diagnostics-specific strategic objectives in the NSP includes the following:

Strategic objective	Relevant text
1.1.1.7	Additional diagnostic tools like LF LAM for PLHIV employed
2.4.1.5	Expand testing for TB among high-risk populations using non-sputum samples
2.12.2	Build the capacity of laboratory staff in TB testing. Refresher training on existing tests and training on new TB diagnostic technologies

Figure 3: Diagnostics-specific objectives in the National Strategic Plan

Given existing strategic objectives to adopt diagnostics that are near POC and usually delivered at the primary health level, the anticipated product use case(s) for the updated urine LAM tests would be at the primary health level. Further validation by country stakeholders would be needed, however it is anticipated that swab-based molecular tests would be at the primary care or district level facilities.

7. Methods

Our analysis utilised the following methodologies: desk reviews, online survey(s), virtual and face to face consultations/interviews with key informants, focusing on the following nine (9) thematic areas:

a) *Regulatory requirements for the introduction of new TB diagnostics at the global and continental level (including WHO and Africa Union)*
b) *Regulatory requirements for the introduction of new TB diagnostics at country level*
c) *Validation, review of evidence and inclusion into policy by national TB program, including use cases*
d) Advocacy and demand creation
e) Early adoption: pricing & financing
f) Early adoption and roll out: health systems & implementation needs
g) Scale up: network improvement/optimization and M&E

The analysis employed a thorough desk review of documents from, inter alia, the National TB Programme (hereinafter NTP), procurement laws and regulations, laboratory sector strategies, and others, and were categorised in a repository as follows:

I. Private Public Mix Documents
II. Partners Documents
III. NTP Documents
IV. NRA Documents
V. Other MOH Documents
VI. Lab Network Documents
VII. Algorithms, Guidelines, and SOPs

to enable triangulation of insights consistent with the nine thematic areas above.

Existing information about national pathways, as well as key informant interviews for more qualitative elements such as pricing levels that would be attractive for NTPs and anticipated barriers in the national policy and regulatory processes, were integrated into the findings.

The analysis involved four distinct stages: inception, data collection, sensemaking/validation, and dissemination.

A. Phase I: Inception

An initial engagement meeting was held with each targeted country's National TB Control Program Directors to map key informants and country stakeholders and developed a standardised questionnaire which was piloted in interviews with Treatment Action Group, Stop TB Partnership, Diagnostic Equity Consortium (DEC) and Access Campaign (Médecins Sans Frontieres).

B. Phase II: Data collection and analysis phase

We conducted a desk review involving a combination of systematic online searches and direct engagement with country stakeholders of existing policies, frameworks and guidelines. This was supported by a DocAnalyser.ai software and further interrogated with prompts. Using a mix of manual searches and AI-powered extraction tools, we extracted relevant data points and consolidated them into a standardized Excel tracker in alignment with the key thematic areas above. In addition, semi-structured interview & focus group discussions with regional and country level key informants

(e.g. ministries of health, national regulatory authorities, global health partners, and civil society organizations) were organized to capture first -hand perspectives, gather insights on barriers and specific regional/national challenges for new TB diagnostic platforms and explore possible strategies to shorten pathways and maximize uptake. Visual roadmaps in Microsoft Office Lucidchart software (https://lucid.app/) was created, mapping out the critical steps and decision points involved in introducing new TB diagnostics in each country along the pathway each new TB diagnostic will take, and defined timelines.

C. *Phase III: Sensemaking and validation*

A virtual validation session took place on 5th May 2025 via Zoom with all key stakeholders identified during the inception phase; to mainly analyse all data and receive feedback from stakeholders' (MOH, Regulatory authority, donors and technical agencies) aiming to facilitate and accelerate market entry and uptake, and communities and advocates desiring transparency in decision-making processes. The engagement and feedback on key findings from the pathway analysis will drive the change in policy to remove barriers for new diagnostic introduction and own country final data set and TB diagnostics developed roadmaps. The final report will be circulated to the NTP and MOH, and regulatory authority representatives before finalisation and wider dissemination.

D. Phase IV: Dissemination

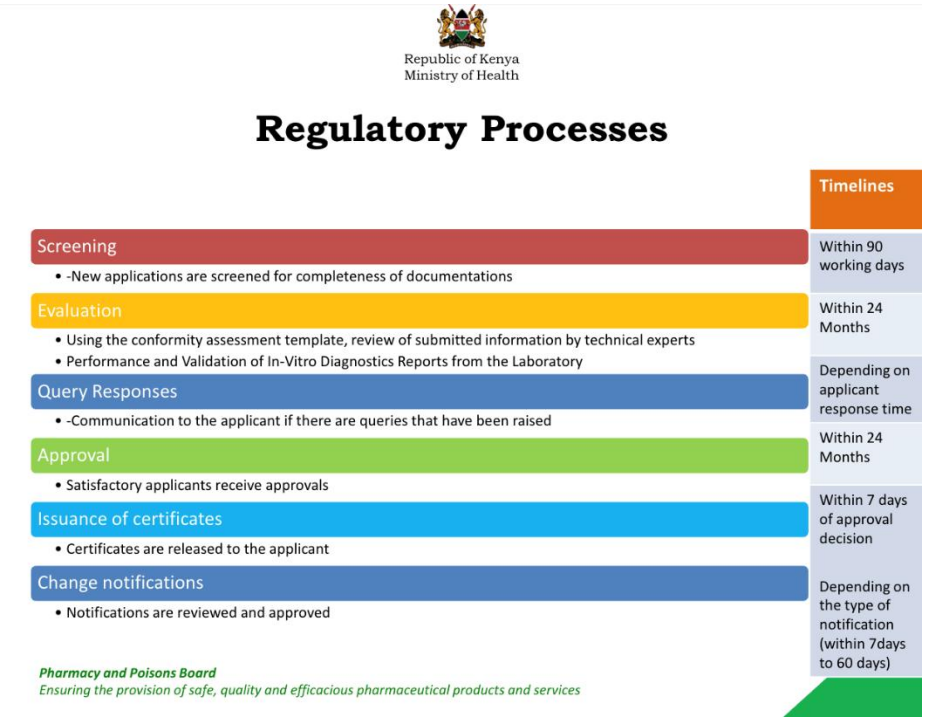
Evidence from this critical path analysis will be integrated into a consolidated global cross-sectional assessment to increase awareness of global stakeholders (manufacturers, donors and global technical and regulatory agencies, etc.) and foster buy in towards the introduction of the new tools. This phase will be led by the Bill and Melinda Gates foundation, McGill University School of Population and Global Health as coordinator of the project, and country NTPs. Dissemination shall occur through different fora such TB TWG meetings at the country level, WHO TB and PQ technical meetings, the summer TB diagnostic courses organized by McGill University School of Population and Global Health, the TB Union world conferences, and via peer review publications.

8. Findings

Overview of the key steps and processes along the path to the introduction of new Dx tools in the country (from approval to implementation & scale up)

A. Regulatory requirements for the introduction of new TB diagnostics at the global and continental level (including WHO and Africa Union)	
Overview of key steps, tasks and parties involved	WHO prequalification not required for regulatory approval in Kenya but is desirable for faster pathway. WHO recommendation deemed essential for inclusion in national TB policy.
Enablers	Kenya deposited the instruments of ratification of the Treaty on the establishment of the African Medicine Agency (AMA Treaty) on 16th July 2023. Kenya is involved and represented on the various AMRH and Africa CDC committees as follows: • Medical Devices Technical Committee (AMDF-TC) Chairperson: Paulyne Wairimu Pharmacy and Poisons Board, Kenya • Regional Centres of Regulatory Excellence (RCORE) in pharmacovigilance: Pharmacy & Poisons Board (PPB) Kenya. • Africa CDC Diagnostic Advisory Committee (DAC) for In-vitro diagnostics (IVDs) member: Mwatilu Mwau, Kenya Medical Research Institute (KEMRI)
Anticipated barriers	According to a recent review written by the AMA, AMRH and Africa CDC (The African Medicines Agency - A potential gamechanger that requires strategic focus, 2025), continental regulatory harmonisation will likely face several barriers, including capacity to handle all product categories, including diagnostics, coordination challenges with NRAs and RECs, political and financial independence, and addressing the gap vis-a-vis locally manufactured products and WHO PQ.
Timelines	Unknown, regional processes ongoing but once established presumed that national pathways will become shorter.

B. Regulatory requirements for the introduction of new TB diagnostics at country level

Overview of key steps, tasks and parties involved	The applicant (manufacturer) will need to compile all relevant documents before applying on the PRIMS platform operated by the Pharmacy and Poisons Board (PPB). This includes clinical and pre-clinical studies, manufacturer certificates, regulatory approvals, post-market surveillance plans, product information (including labelling, instructions for use, and material specifications), risk assessments with possible hazards associated with the device, manufacturing information (including quality plan and manufacturing processes), and quality control lab requirements, among others. Products which already have WHO PQ and/or approvals from reference regulatory authorities for identical/similar use can either undergo an i) abridged or ii) expedited regulatory pathway. (Timelines below) (PPB, January 2025, p. 18-19) Below shows the timeline for a full evaluation in the absence of approvals from other reference regulatory agencies or WHO PQ.  *Figure 4: Regulatory Processes in Kenya. Source: Paulyne Wairimu, Pharmacy and Poisons Board Head, Health Technologies Evaluation and Registration. Presentation on "Overview of Regulation of Medical Devices and IVDs", August 2023* The manufacturer will also need to appoint a local authorised representative for distribution of the products.
Enablers	The World Health Organization (WHO) prequalification is not explicitly required for the adoption or registration of new medical devices or in-vitro diagnostics (IVDs) in Kenya. However, it can significantly facilitate the registration process. According to the guidelines, medical devices with prior approval from recognized stringent regulatory agencies (SRAs), including WHO prequalification, can be used

B. Regulatory requirements for the introduction of new TB diagnostics at country level	
	to abridge the evaluation process for medical devices to be marketed in Kenya (*Pharmacy and Poisons Board Kenya, Guidelines on Submission of Documentation for Registration of Medical Devices, September 2011, page 20*). Hence based on this, WHO PQ is a key enabler that would expedite evaluation. Additionally, completeness of documents will prevent more queries being raised at the query stage.
Anticipated barriers	Manufacturers may have initial confusion as regards the regulatory role of the PPB and KMLTTB. However, a June 2025 legal judgment HCJR/E043/2021 has found that regulatory oversight for IVDs is under the direct oversight of the Pharmacy and Poisons board. **Post-Market Surveillance Requirements:** Manufacturers are required to establish post-market surveillance systems to monitor the performance of their diagnostic tools after they have been introduced to the market. This ongoing obligation can be resource-intensive and may pose additional challenges for manufacturers. (*Pharmacy and Poisons Board Kenya, Guidelines on Submission of Documentation for Registration of Medical Devices, September 2011, p. 22-23*) **Capacity:** the Pharmacy and Poisons Board reports a need for more skilled staff members and specialized capacity building on IVDs – however the documents are unclear as to whether this affects processing times. (Presentation by Pauline Wairimu on *"Overview of Regulation of Medical Devices and IVDs"* 2023)
Timelines	Upon submission of the application, the documents will be screened within **90 days**, after which the evaluation process will begin, taking **up to 24 months** after the completion of the screening process. There will then be a query process with questions from the PPB to the manufacturer. The timeline for this will depend on the amount of clarifications/queries directed at the applicant and the rate of response from the manufacturers. Subject to satisfactory responses, approval shall be received **within 24 months**. Issuance of certificates shall occur **within 7 days** of the approval decision, and further notifications can take **between 7-60 days** depending on the type of notification. Based on this, the maximum amount of time for regulatory approval would be **4 years, 5 months, and 18 days**. This timeline is expedited if the product has WHO PQ or approval by reference regulatory authorities as follows: a) WHO Prequalified products registered through CRP/SRA-CRP and regional expedited pathways: i. ii. iii. Screening and initial evaluation phase (10 working days) Evaluation of additional screening questions (10 working days). First review (70 working Days) = **90 working days (approximately 4 months)** b) Products approved by Reference Regulatory Authorities including (WLA/SRA). i. ii. iii. iv. Screening and scheduling (10 working days) Evaluation of additional information (30 working days) First review (90 working days) Decision phase (15 working days) = **145 working days (approximately 6 months and 3 weeks).** For test validation, Truenat received test validation from the KMLTTB in December 2021, only **three months** after the initial filing from Molbio in September 2021.

C. Validation, review of evidence and inclusion into policy by national TB program, including use cases	
Overview of key steps, tasks and parties involved	While WHO PQ is not technically required for regulatory approval, according to the National TB Programme Director, interviewed in December 2024, WHO PQ is required for MOH adoption into the TB programme and strategy. (*Dr Immaculate Kathure, KoboToolbox Survey,16 December 2024*) The development of Kenya's National Strategic Plan (NSP) for Tuberculosis, Leprosy, and Lung Health 2023/24–2027/28 spanned **approximately 15 months**. The process commenced in October 2022 with a Data Synthesis Workshop aimed at identifying gaps and setting priorities for TB control. This collaborative effort involved stakeholders from various sectors, including government ministries, county governments, supporting partners, and communities affected by TB. The NSP was officially launched in January 2024, marking the culmination of a comprehensive, multisectoral consultative process led by the Ministry of Health and involving key stakeholders, donors, and partners. According to Dr Immaculate Kathure, National TB Programme Director, when new TB products are included in national policies, several key bodies are consulted: 1. **Ministry of Health (MoH)**: The MoH is responsible for the overall coordination and approval of health policies, including those related to TB diagnostics. 2. **County Governments**: Local governments play a crucial role in implementing national policies and adapting them to local contexts. 3. **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. 4. **Donors and Implementing Partners**: These organizations provide funding and technical support, ensuring that new products align with national and international standards. 5. **Regulatory Agencies**: These bodies ensure that new diagnostic tools meet the necessary regulatory requirements for safety and efficacy. 6. **Medical Boards**: Various medical boards contribute to the review and endorsement of new diagnostic products.
Enablers	Established processes for the inclusion of new tests into national policy. Based on discussions at the validation meeting, the NTP is already thinking about the use of these point-of-care tests for use at the primary care network levels, which could expedite decisions on use cases.
Anticipated barriers	I. Slow regulatory approval or guideline/recommendation development by WHO. II. Operational buy-in to involving lay testers [James Sakwa, PMLS, Kakamega County]
Timelines	There is no standard timeline established for the introduction of new TB diagnostics into national policy, according to Dr Immaculate Kathure from the National TB Programme (interviewed December 2024), and approval depends on results of the regulatory assessment and other relevant factors. Some relevant timelines from history are as follows: the development of Kenya's National Strategic Plan (NSP) for Tuberculosis, Leprosy, and Lung Health 2023/24–2027/28 spanned **approximately 15 months**.

C. Validation, review of evidence and inclusion into policy by national TB program, including use cases	
	GeneXpert was adopted in national policy in 2011 and rollout via pilots and received full regulatory approval in 2018. Truenat was officially rolled out in Jun-Jul 2022, approximately 6-7 months after test validation at KMLTTB and 9-10 months after the first filing of the application for test validation by Molbio (filed in September 2021)

D. Advocacy and demand creation	
Overview of key steps, tasks and parties involved	According to the FGD conducted with communities in December 2024, to create demand for new TB diagnostics, several activities and mechanisms should be employed. These include: 1. **Community Engagement**: Utilizing local events, such as health talks during sports tournaments or community gatherings, to raise awareness about TB and the importance of testing. 2. **Media Involvement**: Leveraging local media platforms to disseminate information about new diagnostic tools and their benefits, targeting specific audiences through tailored messaging. 3. **Training and Capacity Building**: Conducting training sessions for community health workers and TB champions to equip them with the necessary skills to educate the community about the new tests. 4. **Advocacy**: Engaging policymakers and stakeholders to ensure that new diagnostics are included in national health strategies and budgets. 5. **Mapping Stakeholders**: Identifying and collaborating with key stakeholders, including community organizations and health facilities, to enhance outreach and support for demand creation efforts
Enablers	Established civil society and community TB networks that can play a robust and persistent role in advocacy and demand creation.
Anticipated barriers	According to a Principal Medical Laboratory Scientist interviewed for this report, refresher trainings are conducted every three years contrary to the guidance on annual trainings/orientations, which is insufficiently frequent. This affects the quality of activity implementation and data due to high turnover of CHWs.[16] According to the FGD with communities held in December 2025, the biggest anticipated barriers to demand creation for new TB diagnostics include: 1. **Supply Chain Issues**: Inconsistent availability of diagnostic tools can lead to stockouts, undermining trust in the testing process. 2. **Resistance from Stakeholders**: Some health workers may be hesitant to adopt new tests due to lack of familiarity or perceived threats to their roles. 3. **Regulatory Challenges**: Delays in the approval and integration of new diagnostics into national health guidelines can hinder timely implementation. 4. **Community Awareness**: Low levels of awareness and understanding about the benefits of new diagnostics can limit community engagement and uptake. 5. **Financial Constraints**: Limited funding and political will at both national and county levels can restrict the resources allocated for demand creation activities. 6. **Cultural Barriers**: Stigma associated with TB may deter individuals from seeking testing, impacting overall demand
Timelines	Advocacy and demand creation is an ongoing process but should begin before the tests are introduced/rolled out.

E. Early adoption: pricing & financing	
Overview of key steps, tasks and parties involved	Pricing for new TB diagnostic tools is influenced by several factors as outlined by Dr Immaculate Kathure from the NTP. There is no standard or fixed price that makes these tools universally attractive for NTPs to invest in. Optimal pricing is context-dependent and varies according to the specific diagnostic tool and its use case. Additionally, while the country has established a national health insurance program that currently includes and reimburses existing TB tests, the inclusion of new TB tests into the national insurance scheme is a phased process, prioritizing widely used tests. Furthermore, concessional pricing does not automatically cover the private health sector, and alternative mechanisms may be needed for private providers to access such pricing Funding for procuring new TB diagnostic tools often depends on donor resources and availability, which can also impact pricing and procurement volumes. Procurement volumes for other TB diagnostics may be illustrative. In 2016, Kenya procured 262,650 GeneXpert cartridges with a 56% utilisation rate at full capacity,[17] however this is with robust donor support. This is also old data, and consultations with country stakeholders will need to occur to calculate expected procurement volumes at market entry based on use case, targets, and historical data.
Enablers	There is some transparency on the prices of these upcoming tests as a result of the TAG 2024 pipeline report.[18] For example, a swab-based molecular test from PlusLife has a price of less than US$4 per test with the instrument costing less than US$150. The urine LAM test from Biopromic is estimated at US$4 per test, whereas the Fujifilm SILVAMP TB LAM test is estimated at US$6.60 per test.
Anticipated barriers	The new health insurance system does not currently cover these tests. Additionally, there are ongoing challenges with donor financing given foreign policy shifts in the West that will compromise financing of new tests.
Timelines	The 2025 Global Fund window 7 for funding requests had a submission deadline of 17 February 2025, with the Technical Review Panel (TRP) meeting convening in March-April 2025 to assess proposals. Final decisions on funding priorities for Kenya are likely to be made in the latter half of 2025, suggesting approximately 6-8 months for decisions and disbursement of Global Fund financing. According to the National TB Programme during the 5th May 2025 validation meeting, the timeline for pricing and financing decisions is estimated at **six to eight months**, with a focus on domestic decision-making due to donor resource constraints.

F. Early adoption and roll out: health systems & implementation needs	
Overview of key steps, tasks and parties involved	**<u>Procurement of tests</u>** ***Steps*** 1. Procurement is initiated per regulation 71 of the **Public Procurement and Asset Disposal Regulations 2020.** The head of the user department must submit a requisition to the head of the procurement function with supporting documentation, including feasibility studies.[19] 2. Technical evaluation and financial evaluation conducted in succession per regulations 76(1) and 77(1) of the **Public Procurement and Asset Disposal Regulations 2020** 3. The accounting officer shall in writing: a) approve award to the successful tenderer; b) seek clarification from the head of the procurement function or the evaluation committee prior to approving or rejecting the award 4. The above constitutes the initial request. This is followed by a quotation or tender process, contract negotiations and legal review, payment processing, pre-shipment documentation, tax exemption, and shipping. Key actors include the National TB Programme and Kenyan Medical Supplies Authority (KEMSA). ***Estimated Volumes*** 1. **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. 2. **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. **<u>Training for Health Systems Readiness and Implementation</u>** 1. 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 2. Additionally, stakeholders suggested: a) Training of medical laboratory technicians to man peripheral medical laboratories in the country & to act as hubs for lay testers. b) Community Health Promoters/TB Champions who meet minimum academic qualifications should be trained on the novel diagnostics and should be provided certificates that are accredited and recognised by the MOH and relevant academic institutions.

F. Early adoption and roll out: health systems & implementation needs	
Enablers	Donors (including Global Fund and USAID) are the primary source of funding for procuring new TB diagnostic tools. Hence it would be an enabler to have established commitment and support from international donors to procure these novel TB diagnostics.
Anticipated barriers	<u>Health systems and programmatic issues:</u> The anticipated implementation barriers for using new tuberculosis (TB) diagnostic tools, as highlighted in the provided documents, include several key challenges: 1. **Shortage of Personnel**: There is a significant shortage of trained personnel, particularly TB coordinators, which poses a challenge in managing the increased data entry burden associated with new diagnostic tools (K*enya Digital TB Surveillance System Assessment Report.pdf page 7*). 2. **Infrastructure Limitations**: The availability and maintenance of necessary hardware, such as desktops, laptops, and tablets for data entry, are inadequate. This limitation affects the ability to report data directly from facilities, leading to delays and increased burdens on TB coordinators (*Kenya Digital TB Surveillance System Assessment Report.pdf page 7*). 3. **Internet Connectivity Issues**: Unreliable internet conditions hinder real-time case-based data entry from the facility level, complicating the effective use of digital tools (*Kenya Digital TB Surveillance System Assessment Report.pdf page 7*). 4. **Access to Mobile Devices**: Gaps in the availability of smartphones among health workers limit the usage of mobile applications designed for TB data collection and management (*Kenya Digital TB Surveillance System Assessment Report.pdf page 7*). 5. **Integration Challenges**: There is a need for better integration of the new diagnostic tools with existing health information systems, such as the TIBU system and other laboratory information systems (*Kenya Digital TB Surveillance System Assessment Report.pdf page 8*). 6. **Funding Constraints**: Expanding the system to include the private sector for TB case reporting requires additional funding, which is often a bottleneck (*Kenya Digital TB Surveillance System Assessment Report.pdf page 7*). 7. **Community Engagement**: The absence of patient/community-centric applications limits access to crucial information for program monitoring and planning, which can affect adherence to treatment and overall program effectiveness (*Kenya Digital TB Surveillance System Assessment Report.pdf page 7*).
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: 1. 2-3 weeks for initial request and Treasury verification 2. 2-3 weeks for quotation or tender process 3. 1 month for contract negotiations and legal review

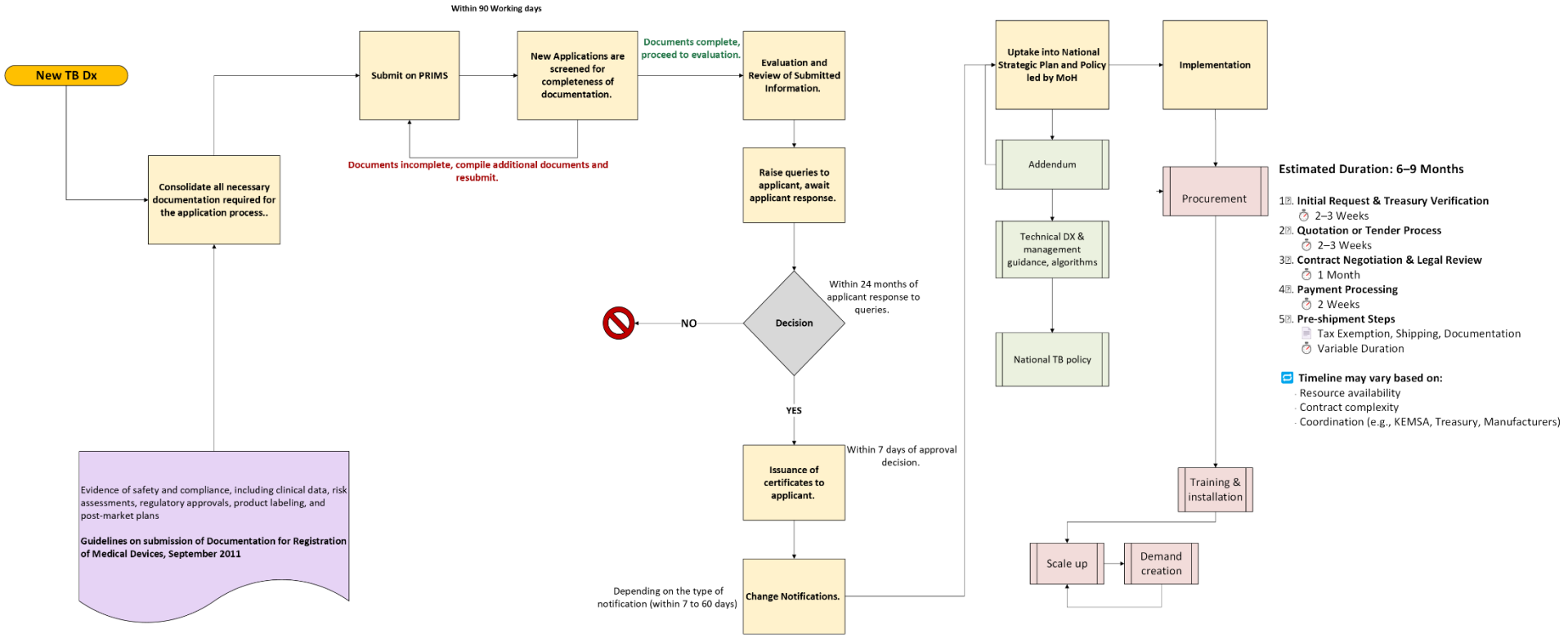
F. Early adoption and roll out: health systems & implementation needs	
	4. 2 weeks for payment processing 5. Additional time for pre-shipment documentation, tax exemption, and shipping. The entire process can stretch up to **9 months**, depending on available resources, complexity of the contract, and coordination between different entities like KEMSA, Treasury, and manufacturers. Training of three cadres will take **at least two (2) years**.

G. Scale up: network improvement/optimization and M&E	
Overview of key steps, tasks and parties involved	**Network improvement/optimization** 1. DNOs not possible each time a new test is introduced. Based on recent history of DNOs (2021 DNO supported by FIND; 2023 diagnostic network assessment supported by USAID), DNOs may take place every two years. **M&E** 1. Based on previous experiences with the introduction of GxLIMS for GeneXpert performance indicators monitoring in 2013, two years after the initial rollout of GeneXpert machines, and the introduction of Tibulims thereafter, we can assume that it would take two (2) years for the introduction of connectivity/M&E solutions. Parties involved that the time included the National TB Programme, the National TB Reference Laboratory (NTRL), and USAID. 2. To effectively integrate electronic reporting for new TB diagnostic tools with national ICT systems, several connectivity solutions are necessary: a) API Integration: Implementing Application Programming Interfaces (APIs) that enable automatic data transfer from diagnostic machines to the national databases to reduce manual data entry errors and improve the speed of reporting (*National Laboratory Reference Laboratory Operational Plan 2023-2028 page 52)* b) Cloud-Based Solutions: Utilizing cloud storage for data archiving and backup, ensuring that all diagnostic data is securely stored and easily accessible for analysis and reporting (*National Strategic Plan for Tuberculosis, Leprosy, and Lung Health 2023-2028, p. 78*) c) Mobile Data Capture Tools: Developing mobile applications, such as T-bu Lite, that allow healthcare workers to enter data directly from the field, which can then be synchronized with national databases (*National Strategic Plan for Tuberculosis, Leprosy, and Lung Health 2023-2028, p. 46*) Training and Capacity Building: Providing training for healthcare workers on the use of these electronic systems to ensure effective data entry and management, thereby enhancing the overall quality of data collected. (*National Strategic Plan for Tuberculosis, Leprosy, and Lung Health 2023-2028, p. 122*) **M&E** The importance of quality assurance and safety for diagnostic tests is emphasized, with a focus on the role of the Kenya Medical Laboratory and Technology Board (KMLTB).
Enablers	Some of the molecular swab tests are produced by Cepheid and Molbio, which may be operable with existing connectivity solutions. Based on this, there may be established expertise in Kenya on these connectivity solutions. However, a key enabler will be the development of collaborations with manufacturers to develop sustainable in-country connectivity solutions. Furthermore, the country has experience with DNOs/DNAs being conducted every two years.

G. Scale up: network improvement/optimization and M&E	
Anticipated 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.
Timelines	Based on the two examples, DNOs occur approximately every two (2) years. The above information about the GxLIMS and Tibulims systems indicates that this can also be done approximately two (2) years after product introduction. Assuming these can be conducted in parallel/simultaneously, we have assumed a timeline of two (2) years for both DNO and introduction of connectivity solutions.

9. Critical Path Analysis country roadmap(s)

Figure 5: Pathway A: General overview of new TB diagnostics introduction in the public sector



Pathway B: New TB diagnostics introduction in the private sector: [Not applicable – the above pathway applies]

Figure 6: Pathway for emergency authorisation

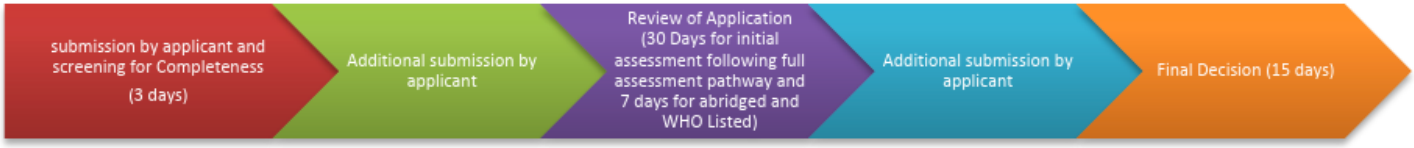
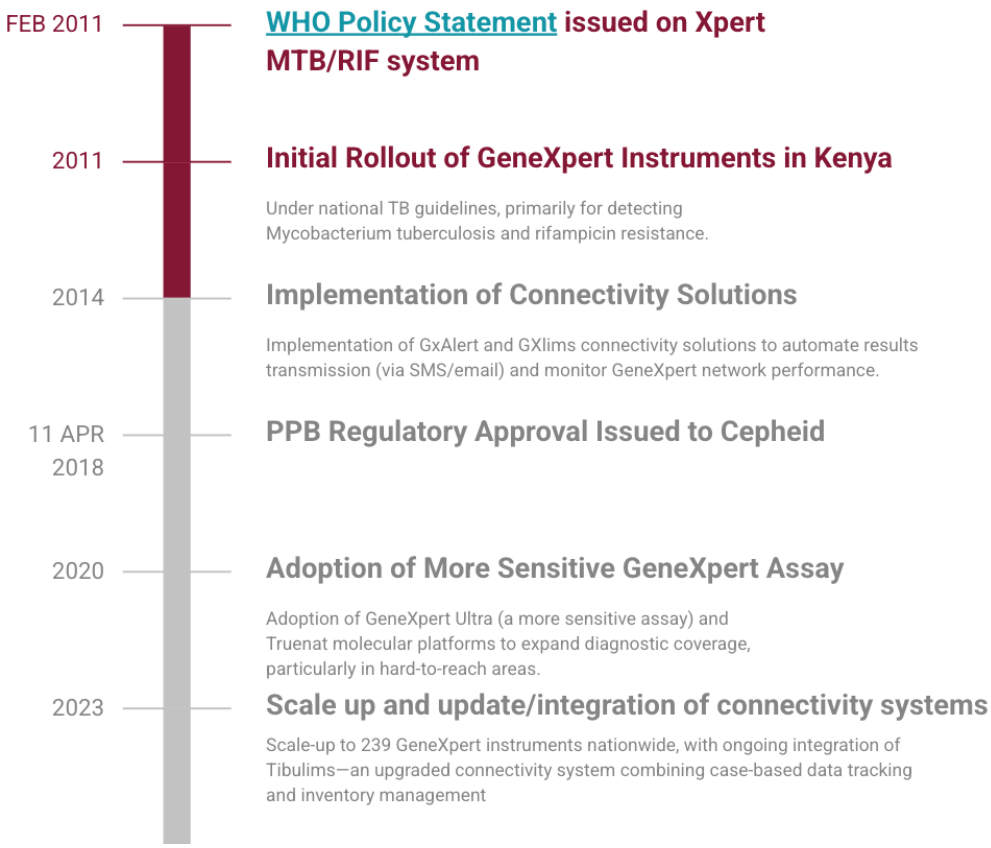
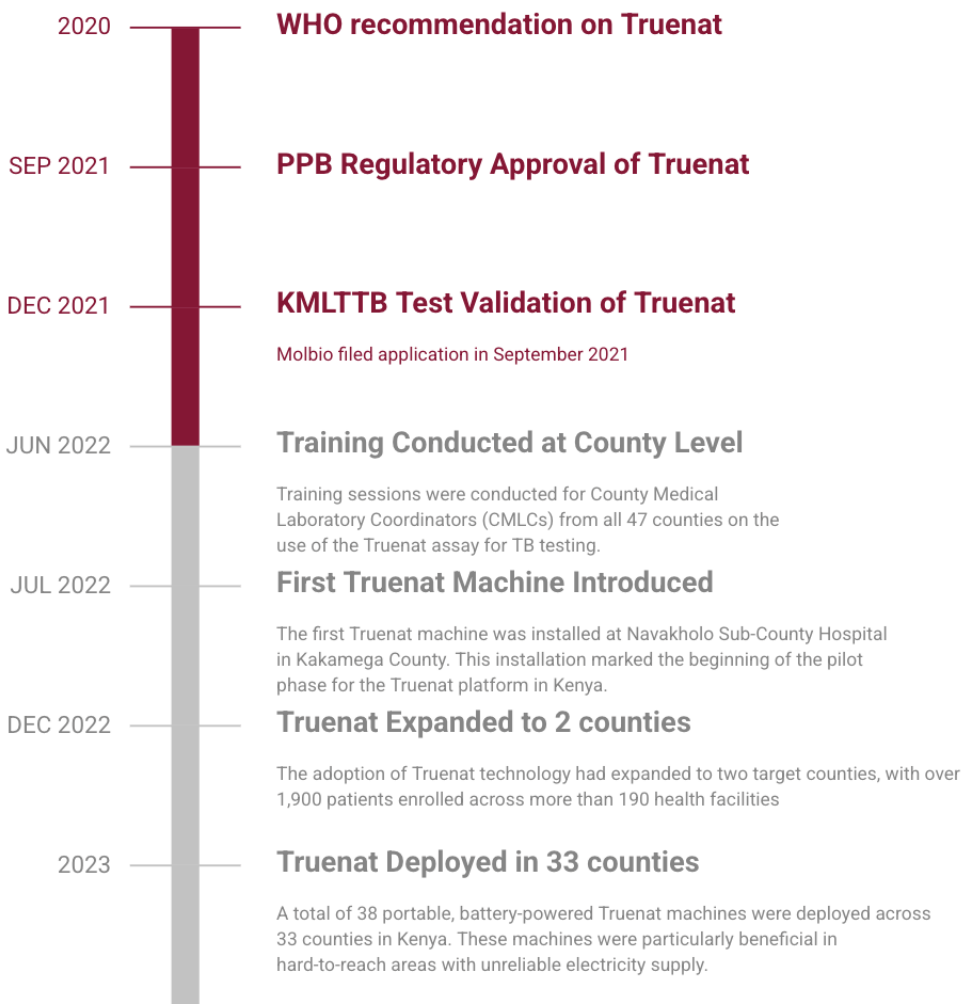


Figure 7: Historical timeline for GeneXpert introduction



Note: Initial rollout of GeneXpert instruments may have occurred under a pilot/research project, hence why PPB regulatory approval appears in the timeline at a later stage.

Figure 8: Historical timeline for Truenat test introduction



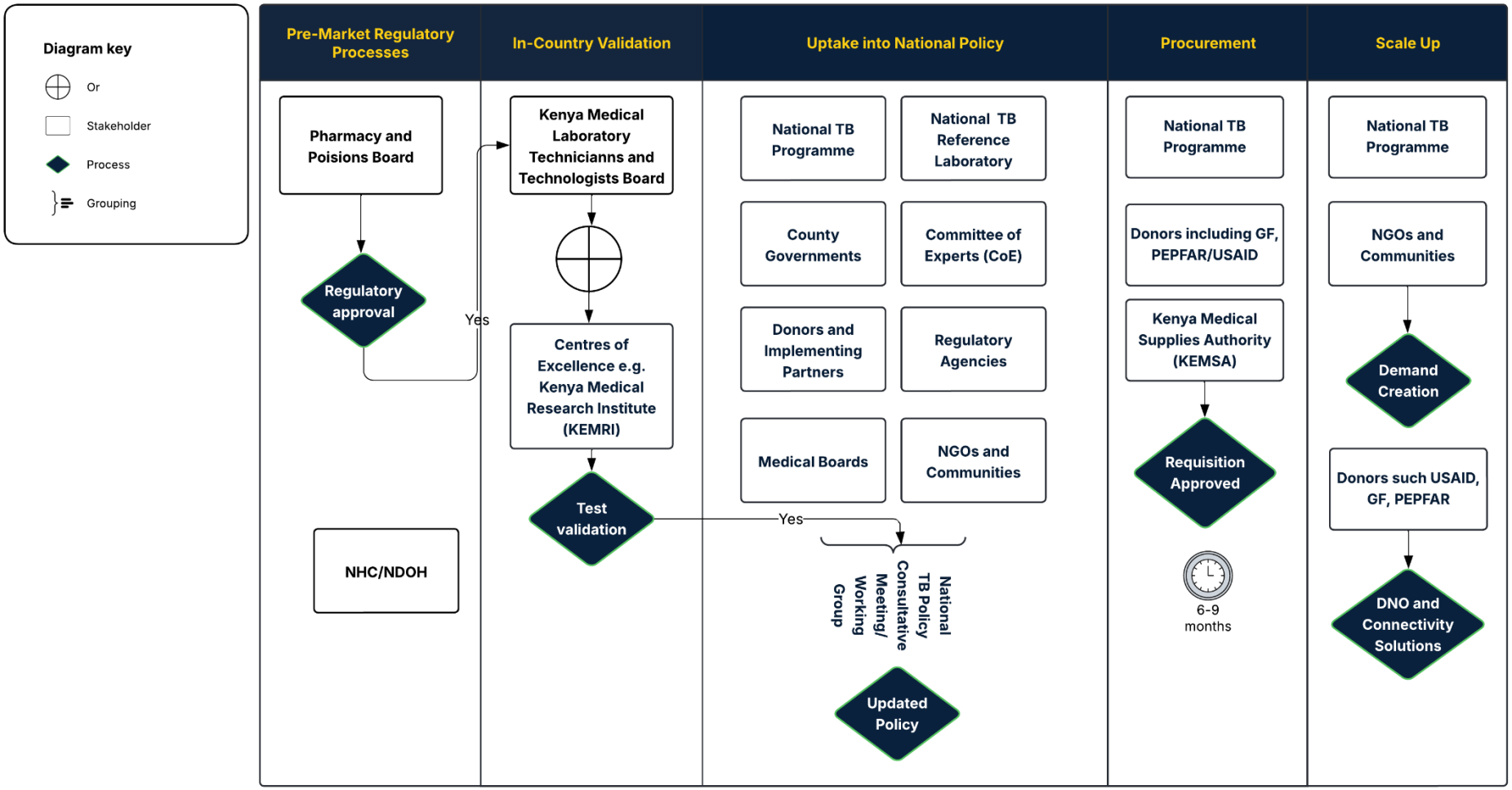
10. Recommendations and conclusions

Based on this critical path analysis in Kenya, we synthesised the following key recommendations for distinct stakeholders:

Recommendations for WHO and PQ teams	▪ As soon as is feasible, to issue clear guidelines and recommendations on novel TB diagnostics.
Recommendations for Donors (Global Fund, Unitaid, etc)	▪ To budget for the inclusion of novel TB diagnostics in country grant planning. ▪ To share findings with test developers under existing projects, such as with the Unitaid-funded DriveDx4TB TOO project (focused on introduction of novel TB diagnostics) to fast-track adoption ▪ To fund advocacy and demand creation ahead of test introduction.
Recommendations for the NTP/MOH to shorten & streamline the critical path	▪ Country national regulatory authorities to provide up-to-date repositories (regulatory guidelines, licensed distributors, etc) to enable ease of access of information for test developers. ▪ Where WHO recommendations are not available, to utilise regional recommendations or recommendations from other stringent regulatory authorities. ▪ Government treasuries to provide adequate resources to national regulatory authorities ▪ Where WHO recommendations are not available, to utilise regional recommendations or recommendations from other stringent regulatory authorities. ▪ Increase capacity of IVD experts inside PPB ▪ Develop clear awareness/summary materials to orient and educate manufacturers on regulatory procedures, including average processing times.
Recommendations for test developers on how to launch a product in the country	▪ To ensure the completeness of documents before submitting on PRIMS, including all manufacturer certifications, pre-clinical and clinical tests, plans for post-market surveillance, etc. ▪ To be aware of conditions for abridged evaluation routes, i.e. regulatory approval for similar use from three (3) other reference regulatory agencies. ▪ To appoint a local authorised representative for distribution of the products. ▪ To ensure transparency and accessibility in product pricing.

11. Appendices

A. Appendix 1: Stakeholders map (roles and responsibilities)



B. Appendix 2: Data sources: Repository of country documents

No.	Title of Document	Publisher/Author	Year of Publication
1.	Guidelines on submission of documentation for registration of medical devices	Pharmacy and Poisons Board	2011
2.	List of regulatory authorities and agencies per state department	Government of Kenya	No date provided
3.	National quality management framework for tb diagnostic laboratories	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2023
4.	National Tuberculosis Reference Laboratory Operational Plan	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2023
5.	Public Procurement and Asset Disposal Regulations 2020	Republic of Kenya	2020
6.	Kenya: Country Commercial Guide	U.S. International Trade Administration	2024
7.	The Pharmacy and Poisons Act	Republic of Kenya	2022
8.	Kenya Medical Supplies Authority Act	Republic of Kenya	2013
9.	National Strategic Plan for Tuberculosis, Leprosy and Lung Health	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2023
10.	Multi-sectoral Accountability Framework to Accelerate Progress to End Tuberculosis in Kenya by 2030	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2022
11.	Treatment of Drug-Resistant Tuberculosis in Kenya	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2020

No.	Title of Document	Publisher/Author	Year of Publication
12.	Job Aid for Clinical Management of TB/HIV	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2019
13.	National Tuberculosis Reference Laboratory Operational Plan	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2023
14.	National quality management framework for TB diagnostic laboratories	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2023
15.	Interim management guide for tuberculosis and covid-19	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2022
16.	Guidelines on the programmatic management of drug resistant tuberculosis	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2021
17.	Integrated Guideline for Tuberculosis, Leprosy and Lung Disease	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2021
18.	Standard operating procedures (SOP) for the management of tuberculosis in children	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2017
19.	Drug-resistant tb standard operating procedures	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	
20.	Kenya Country Operational Plan (COP/ROP)	PEPFAR	2023
21.	Kenya Digital TB Surveillance System Assessment Report		
22.	TB CARE I Final Full Report	USAID	2010-2015

23.	Public-Private Mix Action PLan	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2021
24.	Overview of Regulation of Medical Devices and IVDs, Powerpoint Presentation	Paulyne Wairimu, Pharmacy and Poisons Board	2023
25.	Guidelines on Submission of Documentation for Registration of Medical Devices	Pharmacy and Poisons Board Kenya	September 2011
26.	20250106 James Sakwa 06 01 25.docx	James Sakwa	January 2025
27.	amrh_nepad_Kenya.pdf	Kenya _ AUDA-NEPAD- AMRH_webpage	2024
28.	A LIST OF REGULATORY AUTHORITIES AND AGENCIES PER STATE DEPARTMENT.pdf		
29.	Nairobi CSO Consultation_otter_ai.pdf	CSO and Communities, Kenya	2024
30.	NATIONAL QUALITY MANAGEMENT FRAMEWORK FOR TB DIAGNOSTIC LABORATORIES 2023 - 2028	National TB Reference Laboratory	2023-2028
31.	Kenya Medical Supplies Authority Act, Revised Edition 2022	KEMSA	2022
32.	KEMSA Public Procurement and Asset Disposal Regulations-2020	KEMSA	2020
33.	CommercialGuide_Kenya.pdf		July 2024
34.	Dr Immaculate Kathure, Kobo Toolbox Interview	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	16 December 2024
35.	Multi-sectoral Accountability Framework to Accelerate Progress to End Tuberculosis in Kenya by 2030	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2022
36.	Treatment of Drug Resistant Tuberculosis in Kenya - Introduction of the Injectable Free Regimens 2020	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2020

37.	GUIDELINES ON THE PROGRAMMATIC MANAGEMENT OF DRUG RESISTANT TUBERCULOSIS 2021	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2021
38.	INTERIM MANAGEMENT GUIDE FOR TUBERCULOSIS AND COVID-19-2022	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2022
39.	STANDARD OPERATING PROCEDURES (SOP) FOR THE MANAGEMENT OF TUBERCULOSIS IN CHILDREN, 2ND EDITION	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2017
40.	Simplified Algorithm for the Diagnosis of Pulmonary Tuberculosis in Children (aged below 15 years)	Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	2024
41.	TB CARE I FINAL REPORT 2010 - 2015	USAID	2015
42.	Stop TB partnership Kenya Digital TB Surveillance System Assessment Report	Stop TB Partnership	
43.	USAID KENYA TUBERCULOSIS ROADMAP OVERVIEW, FISCAL YEAR 2024	USAID	2024
44.	Fiscal Years (FY) 2024 and 2025 PEPFAR Planned Allocation	PEPFAR	2023
45.	Kenya -Customs Regulations-International Trade Organization-2024	International Trade Organization	2024
46.	Association of Medical Laboratory Diagnostics Suppliers vs Kenya Medical Laboratory Technicians and Technologists Boards and Pharmacy and POISONS Board (*HCJR/E043/2021)*	Republic of Kenya: Milimani Law Courts	2025

C. Appendix 3: Lists of key informants (and interview modalities: face to face consultation vs electronic submission)

No.	Name	Position and Affiliation	Interview modalities
1.	Dr Immaculate Kathure	NTP Manager, Ministry of Health: National Tuberculosis, Leprosy, and Lung Disease Programme	Face to face consultation & electronic submission
2.	Dr Titus Mutwiri	Chairman, Kenya Medical Laboratory Technicians & Technologists Board (KMLTTB)	Face to face consultation
3.	James Sakwa	Principal Medical Laboratory Scientist, Kakamega, Kenya	Electronic submission
4.	Evaline Kibuchi	Chief National Coordinator, Stop TB Partnership-Kenya	Face to face consultation
5.	Dorothy Adongo	Coordinator, African Initiative for Global Health, Advocacy, and Policy (AIGHAP) and TB Champion/Community health worker, Bungoma county	Face to face consultation
6.	Lucy Adalla	TB Champion/Community health worker, Bungoma county	Face to face consultation
7.	Camilla Mwathimba	TB Champion/Community health worker, Westlands Subcounty, Nairobi	Face to face consultation
8.	Josphat Asande	TB Champion/Community health worker, Westlands Subcounty, Nairobi	Face to face consultation
9.	Rose Mbithe Mathendu	TB Champion/Community health worker, Makadara Subcounty, Nairobi	Face to face consultation
10.	Samuel Wainaina Ngaruiya	TB Champion/Community health worker, Embakasi Subcounty, Nairobi	Face to face consultation
11.	Jane Wanjiru	TB Champion/Community health worker, Kamukunji Subcounty, Nairobi	Face to face consultation
12.	Peter Mungori	TB Champion/Community health worker, Embakasi East Subcounty, Nairobi	Face to face consultation

D. Acceptance of Findings by National TB Programme

The National TB Programme, Ministry of Health hereby acknowledges and accepts the content of the report as complete and satisfactory. By signing this agreement, the National TB Programme confirms that the findings may be relied on for the next steps in introducing novel TB diagnostics in the country.

Signed,

Dr. Immaculate Kathure, *OGW*
AG. HEAD DIVISION OF TUBERCULOSIS AND OTHER LUNG DISEASES, MINISTRY OF HEALTH
REPUBLIC OF KENYA

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