MATAHARI

Critical Path Analysis of New TB Diagnostics in Africa

Final report

Nigeria

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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 (i.e.: swab based near-POC molecular tests and next generation lateral flow/LAM assays) that offer potential to expand access to TB testing services, especially at decentralized level. In the current global context of stalled progress toward WHO targets for universal access to rapid TB diagnosis and shifting donor landscapes, the CPA provides a consolidated roadmap to shorten time to impact and inform manufacturers, funders, regulators and national program leaders. Nigeria ranks among the top 8 high TB burden countries globally and contributes 4.8% of estimated new TB cases worldwide in 2024. As Africa's most populous nation, the country presents a critical case for optimizing the introduction of new TB diagnostics.

The CPA has identified the following key enablers:

- *Governance:* The National Tuberculosis, Buruli and Leprosy Control Program (NTBLCP) policies support decentralized testing and innovation.
- *Regulatory ecosystem:* Established frameworks underpin the registration and importation of medical devices and *in vitro* diagnostics (IVDs) through the National Agency for Food and Drug Administration and Control (NAFDAC), the Medical Laboratory Science Council of Nigeria (MLSCN) and the Standards organization of Nigeria (SON). Pathways for abridged registration include the WHO collaborative procedures as well as the Emergency Use Authorization (EUA). Additionally, NAFDAC achieved WHO Global Benchmarking Tool (GBT) maturity level 3 in 2022 and pioneered the new GBT plus Medical Devices benchmarking in November 2024.
- *Policy Uptake*: Academic institutions, local non-governmental organizations (NGOs) and technical partners supporting operational research and local evidence generation, and the availability of a National Essential Diagnostics List (NEDL), facilitate integration into national policy.
- *Advocacy and Demand Generation:* High-level political support from the First Lady and Governors' Wives as TB Ambassadors, coupled with effective media engagement and community-level health promotion. A successful Private Public Mix (PPM) model and targeted outreach strategies expand access for vulnerable populations.
- *Financing and procurement:* eligibility for the Global Fund near POC access fund will allow pilot roll-out of the MiniDock MTB test, the prototype for the new class of near POC and swab compatible rapid molecular diagnostics for TB, in early 2026.

Conversely, the following key challenges have been identified:

- *A complex regulatory ecosystem*: Parallel registration pathways (NFADAC and MLSCN) create uncertainty and administrative burden for manufacturers, which are compounded by additional requirements from SON for imported testing devices.
- *Financial constraints threatening sustainability*: A 73% gap in programmatic funding, systemic challenges (limitations in workforce, infrastructure gaps, insufficient public services (internet and electricity)) and poor integration with other sectors, limit domestic capacity for sustaining externally funded pilot projects. Coverage of the National Health Insurance Scheme (NHIS) remains low (around 5%).
- *Procurement:* Heavy reliance on external funding, long lead times for product delivery, fluctuations in local currency and late disbursements leading to reagent stock-outs.
- *Impact of recent cuts in external funding*: termination of 1,800 staff across 18 high-burden states negatively impacting patient outreach and testing activities, especially for displaced and migrant populations.

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 approval:* NAFDAC: regular approval ~120-240 days (depending on class); collaborative registration ~90 days; EUA ~14 days. MLSCN: regular validation and listing within 4 months; within 90 days for WHO prequalified products.
- *Evidence to policy*: historically ~12 months from WHO endorsement to inclusion into national policy
- *Procurement:* Planning to start 1 year prior to implementation, and from 3 up to 8 months for procurement. At least 11 days for SONCAP processes (for importation and clearance of testing devices).
- *National scale up*: ~6 months from policy inclusion to initial roll out and up to 3 years from pilot to nationwide scale up.

Based on the above, Nigeria CPA informed the following **priority recommendations:**

- *For National Regulators (NAFDAC, MLSCN, SON):* Clarify and connect potentially duplicative processes to reduce manufacturer burden. Advocate for ratification of the Africa Medicine Regulatory Agency/AMA treaty. Continue strengthening medical devices and IVD regulations in line with WHO GBT plus medical devices.
- *For Nigeria Federal Ministry of Health (FMoH) and NTBLCP:* Develop a costed plan for transitioning laboratory system strengthening from external to domestic funding with clear targets and timelines. Ensure timely implementation of the MiniDock MTB pilot under the Global Fund NPOC Access Fund. Integrate TB diagnostics into the National Health Insurance Scheme (NHIS) and Basic Healthcare Provision Fund (BHCPF) to reduce out of pocket expenditures.
- *For In-country Technical Partners & Civil Society:* Maintain support for operational research informing optimal tool introduction. Support community-led monitoring to strengthen advocacy and feedback mechanisms.
- *For test developers / manufacturers:* Ensure dossier completeness per NAFDAC, MLSCN, and SON guidelines. Leverage in-country technical expertise for pre-registration performance evaluation. Ensure full registration of products following market entry.
- *For WHO / PQ teams and continental regulatory actors:* Expedite the review of evidence and publication of policy recommendations for novel diagnostics. coordinate with AMA/AMRH to ensure continental joint-review scope includes TB diagnostics and avoid duplication.
- *For Donors:* Incorporate cost-effectiveness analysis into market shaping initiatives. Support the dissemination of findings from this CPA to inform market entry strategies for new TB (and other as applicable) diagnostic tools.

Conclusion

Established regulatory frameworks and strategic plans, as well as openness to innovation, provides a strong foundation for the introduction of new TB diagnostic tools in Nigeria. However, reliance on external funding, parallel regulatory pathways, and infrastructure gaps present hurdles. With 73% of financing unmet for implementation of TB control activities, and reduction in external funding support, accelerating domestic resource mobilization is crucial to sustain progress. Ensuring universal access to rapid TB testing at decentralized level hinges on coordinated action: streamlining regulatory pathways, leveraging the Global Fund near POC market access initiative and partnerships to ensure timely introduction and scale-up of innovative TB diagnostics, ultimately improving patient outcomes.

Contents

Acknowledgements and Impressum

This report was developed by Matahari Global Solutions Sdn Bhd, registered in Malaysia, Company Registration No. (1339222-9) and was jointly authored by Marguerite Massinga Loembe (senior consultant health systems strengthening and project lead), Fifa Rahman (principal consultant and focal point for Kenya), with contributions by Sam Acellam (associate consultant: health data analytics) for flowcharts and figures, and John Oladejo (independent consultant) for stakeholder engagement.

This document outlines the methodology used to collect, collate, and validate publicly available data to define a critical pathway analysis (CPA) for new tuberculosis (TB) diagnostics. It aims at providing in-depth understanding and documentation of the key steps, timelines, and interdependencies for the market entry and placement of new TB tests that will assist countries in the selection and placement of high-quality TB diagnostics appropriate for their setting, guide donors and test developers/manufacturers in the selection of optimal strategies to accelerate entry new diagnostic tools and that will, overall, complement ongoing initiatives focused on market shaping and increasing access to TB diagnostics in low- and middle-income countries (LMICs).

Matahari would like to thank Puneet Dewan and Chase Mertz (the Gates Foundation) as well as Madhukar Pai, Zarin Abdullah, and Mikashmi Kohli (McGill University Department of Global and Public Health) for the technical and financial resources provided for the project. We also wish to thank Obioma Chijioke-Akaniro, M&E Manager NTBLCP for early support to the project as well as the numerous national experts and stakeholders involved in this process, including representatives from professional bodies, the civil society, manufacturers as well as the private sector (listed in Annex III of this report) for their invaluable insights and contributions.

List of figures

Abbreviations

Africa CDC	Africa Center of Disease control
AIDS	Acquired Immune Deficiency Syndrome
AMA	Africa Medicine Agency
AMRH	African Medical Regulatory Harmonization program
AU	Africa Union
BHCPF	Basic Healthcare Provision Fund
CAD	Computer-aided detection
DR-TB	Drug Resistant Tuberculosis
DST	Drug Susceptibility Testing
ECOWAS	Economic Community of West African States
EQA	External Quality Assurance
ERPD	Expert Review Panel for Diagnostics
EUA	Emergency Use Authorization
FMoH	Federal Ministry of Health (of Nigeria)
GDF	Global Drug Facility
GBT	(WHO) Global Benchmarking Tool
GDP	Gross Domestic Product
HIV	Human Immunodeficiency Virus
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IHVN	Institute of Human Virology Nigeria
IMDRF ToC	International Medical Device Regulators Forum Table of Content
iNTP	Introducing new tools project (USAID/Stop TB partnership)
IDPs	Internally displaced populations
TB-LAM	Tuberculosis lipoarabinomannan (lateral flow) assay
TB LAMP	Loop-mediated isothermal amplification assay
LIC	Low Income Country
LGA	Local Government Area
LQMS	Laboratory Quality Management System
MDR/RR-TB	Multidrug resistant/rifampicin resistant TB
MLSCN	Medical Laboratory Science Council of Nigeria
MoU	Memorandum of Understanding
NAATs	Nucleic acid amplification tests
NAFDAC	National Agency for Food and Drug Administration and Control
NGO(s)	Non-Governmental Organizations
NPOC	Near point of care
NTBLCP	National Tuberculosis, Buruli and Leprosy Control Program
PHC	Primary Health Care
PID	(NAFDAC) Port Inspection Directorate
PLHIV	People Living with HIV
POC	Point of Care
PPM	Private Public Mix (for TB)
QMS	Quality Management System
SON	Standards organization of Nigeria
SOP	Standard Operating Procedure
STBLCP	State TB and Leprosy Control Program
TB	Tuberculosis
UHC	Universal Health Coverage
UN	United Nations
USAID	United States Agency for International Development
VBM-R&R	Vaccines, Biologics and Medical Devices Registration & Regulatory Affairs
WAHO	West Africa Health Organization
WHO	World Health Organization
WHO-PQ	WHO-Prequalification
WRD(s)	WHO-recommended rapid diagnostic(s)

Introduction

Context and rationale for the Critical Path analysis.

Since 2011, highly specific and sensitive rapid molecular tests have transformed the Tuberculosis (TB) diagnostic landscape. Furthermore, during the 2023 United Nations (UN) high level meeting, countries committed to the ambitious goal of having 100% of diagnosed TB cases initially tested with a World Health organization (WHO)-recommended rapid diagnostics (WRDs)[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) which is a critical bottleneck to achieve the objectives of the End TB Strategy by 2030.

In line with what is seen with diagnostics in general, the gap is exacerbated at primary health care [2] and in those groups with paucibacillary loads such as such as children, people living with HIV (PLHIV), and in early-stage disease.[3] Critical transitions are needed to overcome this diagnostic gap, notably including shifting from microscopy to molecular testing, expanding access to decentralized, point of care (POC) or near POC nucleic acid amplification tests (NAATs) and using alternative, non-sputum based, samples such as urine and oral swabs.[4]

Recent and upcoming innovations in TB diagnostics can increase access to testing and bring tests closer to communities. According to the Treatment Action Group's 2024 Pipeline Report, there are several upcoming near or point-of-care (POC) tests that can be used at primary health care centers to diagnose these missing cases. These include 36 new NAATs, including swab-based, and 6 next generation TB lipoarabinomannan (TB-LAM) tests. Furthermore, a recent preprint has reported similar accuracy between swab based and sputum-based molecular tests, fulfilling the WHO Technical Product Profile requirements, and which could potentially make universal molecular testing for TB a reality [5].

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

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[1] Political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis. United Nations. 2023. Accessed 1july 2025
[2] Yadav H. et al., Availability of Essential Diagnostics in Ten Low-Income and Middle-Income Countries: Results from National Health Facility Surveys. *Lancet Glob Health* 2021
[3] de Nooy A. et al., Trade-Offs between Clinical Performance and Test Accessibility in Tuberculosis Diagnosis: A Multi-Country Modelling Approach for Target Product Profile Development. *Lancet Glob Health*, 2024
[4] Pai, M. et al, Transforming Tuberculosis Diagnosis. *Nat Microbiol*, 2023
[5] Steadman, A. et al, Diagnostic accuracy of swab-based molecular tests for tuberculosis using novel near point-of-care platforms: A multi-country evaluation *MedRxiv*, 2025. Accessed 1july 2025

Country profile

Nigeria is a federation of 36 autonomous states with the addition of the Federal Capital Territory, with a population of 233 million in 2024, the most populated country in Africa and 6th globally, and it is classified in the lower middle-income country income group by the World Bank. The country confronts multiple issues, such as safety concerns in its northeastern and northwestern areas, and insufficient state capacity in many regions resulting in limited service delivery and infrastructure gaps, with nearly half of the population living below the poverty line[6]. Nevertheless, according to the African Development Bank, Nigeria's economy grew 2.9% in 2023 and is projected to grow by 3.2% in 2024 and 3.4% in 2025, due to improved security, higher oil production, and stronger consumer demand.

Table 1. Nigeria socio-economic profile (World Bank, 2025)

Population Total (2024)	**232,679,478**
Poverty head count ratio at 3 USD a day (2022)	**41.8 %**
Life expectancy at birth (2023)	**54 years**
Populations growth per annum (2024)	**2.1 %**
Human Capital Index (HCI) (2020)	**0.4**
GDP per Capita (2024)	**806.95**
Unemployment (2024)	**3 %**
Inflation (2024)	**33.2 %**

According to WHO 2025 Global TB report[7], **Nigeria ranks among the top 8 high TB burden countries in the world** and has **the highest burden in Africa**, contributing to 4.8% of estimated new TB cases globally in 2024. The country faces a **triple high burden of TB, MDR/RR-TB and HIV-associated TB**. The disease primarily affects low-income populations, with 54% of people affected by TB unable to afford treatment costs, and with children, nomadic and displaced populations representing the most vulnerable groups experiencing poor TB detection and treatment outcomes[8]. Tuberculosis is within the top 10 causes of death[9] in Nigeria and remains a major public health crisis with 56,000 deaths recorded in HIV-negative people and 5,800 deaths among PLHIV in 2024, though the country has made consistent progress in reducing mortality by up to 50% over the last few years. Furthermore, through concerted efforts with partners, the country has expanded capacity for TB diagnostics with molecular testing platforms (Genexpert, Truenat and TB-LAMP), leading to a steady increase in case notifications since 2019, and with 69% accessing a WRD at the time of diagnosis in 2024.

[6] Nigeria country profile. World Bank Group. Accessed 15th December 2025.
[7] Global TB report 2025. WHO, 2025
[8] Totulope J.O et al. Ending tuberculosis in Nigeria: a priority by 2030. *BMJ Global Health*. 2024.
[9] Nigeria country profile, WHO data hub. WHO 2025. Accessed 4 December 2025.

Population	233 million
Total TB incidence , 2023:	2219 per 100 000 (520 000)
MDR/RR-TB incidence, 2023:	3.5 per 100 000 (8200)
Notified cases of TB, 2023:	402 051
% tested wit WRD:	**69%**
WB classification:	LMIC
TB funding, 2024:	18% domestic **82 % international** (Global Fund, USAID, PEPFAR etc.)

Figure 1: TB Profile-Nigeria *(Source: World TB Report 2025)*

Over recent years, Nigeria has made significant strides in towards the goal of Ending TB by 2030, successfully increasing TB case notification and reducing TB associated mortality.

However, high dependence on external donors and funding shortfalls from reduced development assistance in 2025 threaten current achievements, emphasizing the critical need to prioritize domestic resource mobilization and maintain tuberculosis as a high-priority item on the national policy agenda[10].

National strategic priorities to address the TB epidemic

TB control activities in Nigeria are coordinated by the **National Tuberculosis and Leprosy Control Program (NTBLCP)** at the national level. The NTBLCP is a division of the Federal Ministry of Health (Department of Public Health), and provides policy, technical leadership, resource mobilization, oversight to the National TB & Leprosy Training Centre and National Reference Laboratory, procurement/distribution of TB commodities, program supervision, and coordination of partners.[11] The NTBLCP is headed by a National Coordinator who leads a team of medical officers, laboratory scientists and support staff. Each state has a **State TB and Leprosy Control Program (STBLCP)** under the State Department of Public Health or Primary Health Care. The STBLCP (headed by a STBLCP manager) coordinates TB/leprosy activities in the state, provides secondary care, technical assistance to **Local Government Areas (LGAs),** and implements state operational plans.[12] LGAs are the basic management unit and the operational level where services are delivered through DOTS clinics and facility-level staff under the supervision of a Local Government TB/Leprosy Supervisor (LGTBLS); LGAs implement activities and report up to the State[8].

A detailed map of national stakeholders illustrating their roles along the critical pathway is included in figure 5 of this report.

[10] Sadikin B.g., Ali Pate M., Javier Herbosa T. Motsoaledi P.A. Opinion: To end TB, time for us to own our disease response and financing for health. *Devex*. Oct 2025.
[11] National Strategic Plan for Tuberculosis Control 2021 – 2026. Nigeria FMoH. 2021
[12] End-Term Review of Nigeria's National Strategic Plan for Tuberculosis Control 2015- 2020. Nigeria FMoH. 2020

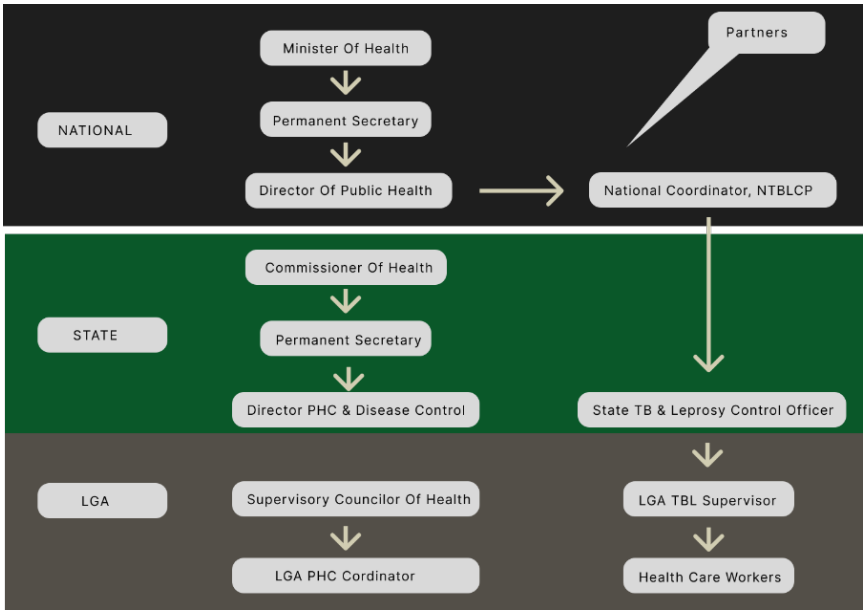

Figure 2: Organization & operational levels of Nigeria NTBLCP (*source: NTBLCP website*)

NTBLCP national strategic plan[13], promotes the adoption of innovative tools and decentralization to lower tiers of the lab network and the community level to further expand access to diagnostic testing services, notably to reach out to the following key affected populations: PLHIV, contact cases, nomads, internally displaced populations (IDPs), inmates, people with diabetes, children, health care workers.

The TB laboratory network in Nigeria is organized in a pyramidal structure including 4-tiered levels as illustrated below:

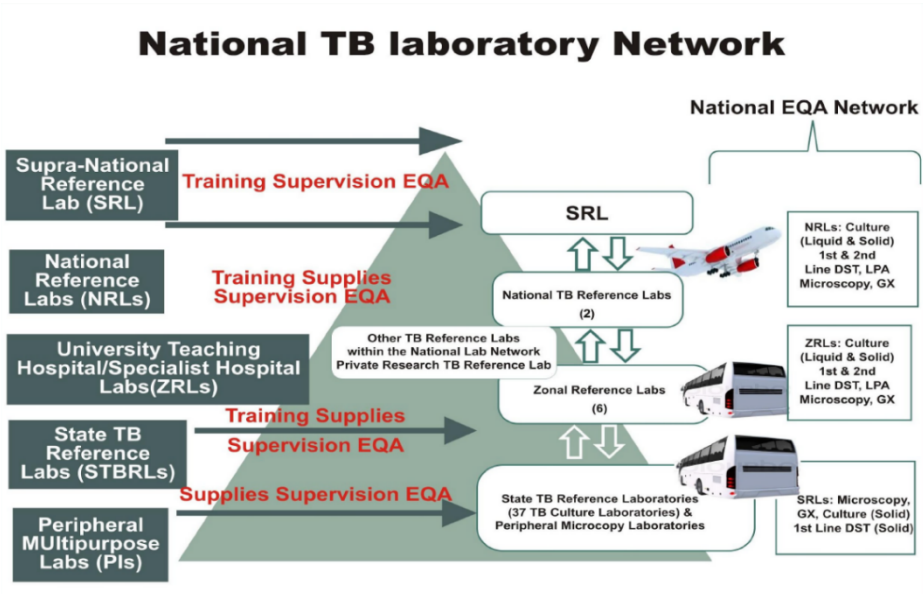

Figure 3: Organization of Nigeria national TB laboratory network *(source: TB NSP 2021-2026)*

[13] National Strategic Plan for Tuberculosis Control 2021-2026 (pages 31-35). Nigeria FMoH. 2021

Public sector:

The NTBLCP aims to ensure coverage for access to TB diagnostic services across the various tiers as follows :

- **Level 1 (peripheral):** laboratories located within primary health centers, general hospitals, specialist hospitals and local government health clinics, with a target coverage of ~100 000 persons/ lab.
- **Level 2 (state):** one laboratory per state, including the Federal Capital Territory (37 in place) with a target coverage of ~3 million persons/ lab.
- **Level 3 (zonal):** reference laboratories located in tertiary health facilities (6 in place) with a target coverage of ~29 million persons/ lab.
- **Level 4 (national):** 2 national reference laboratories (NRLs)
    - the Nigerian Institute of Medical Research (NIMR), Lagos, parastatal, serving the Southern region.
    - the National TB and Leprosy Training Centre (NTBLTB), Zaria, serving the Northern region.
    - The NRLs are affiliated with Milan Supranational Reference Laboratory (SRL) in Italy for the purpose of technical support and external quality assurance.

The NTBLCP also collaborates with laboratory services from private, faith-based, military, and paramilitary health facilities for the provision of diagnostic services. The algorithm for diagnosis of TB in Nigeria is presented in Annex I of this report.

Private sector:

It is estimated that 60% of Nigeria's population, including individuals with symptoms suggestive of tuberculosis, initially seek medical care through private sector facilities[14]. Nigeria has accordingly adopted a multi-stakeholder approach that incorporates initiatives designed to enhance engagement from communities, civil society groups, and private sector entities in TB control activities in collaboration with the NTBLCP. These initiatives have been funded by multiple donors with implementation lead by local NGOs (e.g.: the Institute of Human Virology Nigeria/IHVN, Knowledge Network for Disease Control and Vigilance/KNCV Nigeria, Jana Health Foundation, etc.) with some representative examples listed below:

- The Global Fund **Public Private Mix (PPM) scale-up project** [15] (during the grant cycle 6 and reconducted during grant cycle 7) based on a tripartite agreement between private facilities, HIVN and the NTBLCP, with exact modalities for TB services expansion using a hub and spoke model as detailed in a paper by Taofeekat Ali *et al* and illustrated in figure 4 below [16].
- USAID **TB Local Organizations Network** (TB-LON) and **Tuberculosis Implementation Framework Agreement** (TIFA) projects.
- Stop TB Partnership **TB REACH** and **Challenge Facility for Civil Society** projects (multiple funding rounds).

These approaches allowed expansion of TB diagnostic services delivery through private not-for-profit faith-based hospitals/clinics; private for-profit hospitals/clinics; private standalone laboratories; and retail outlets (patient medicine vendors and community pharmacies). This was complemented by mobile and community-based outreach using ultra-portable digital X-ray with computer-aided detection (CAD) and Truenat in correctional centers, markets, motor parks, etc. as well as hotspot community screenings. Together, this has led to a significant

[14] Obioma Chijioke A. *et al*, Strategic Engagement of Private Facilities to Increase Public-Private Mix (PPM) Contribution to Nigeria Tuberculosis Case Notification. *Journal of Tuberculosis Research*. 2022.
[15] Factsheet : Global Fund TB Public Private Mix. IHVN. Accessed 15 Dec 2025.
[16] Ali T. *et al*. Partnering with the private laboratories to strengthen TB diagnostics in Nigeria. *J. Clin. Tuberc. Other Mycobact. Dis.* 2023

progression in TB case reporting, with the **share of total national TB case notifications from private stakeholders increasing from 10% to 21% between 2017 and 2021**[14].

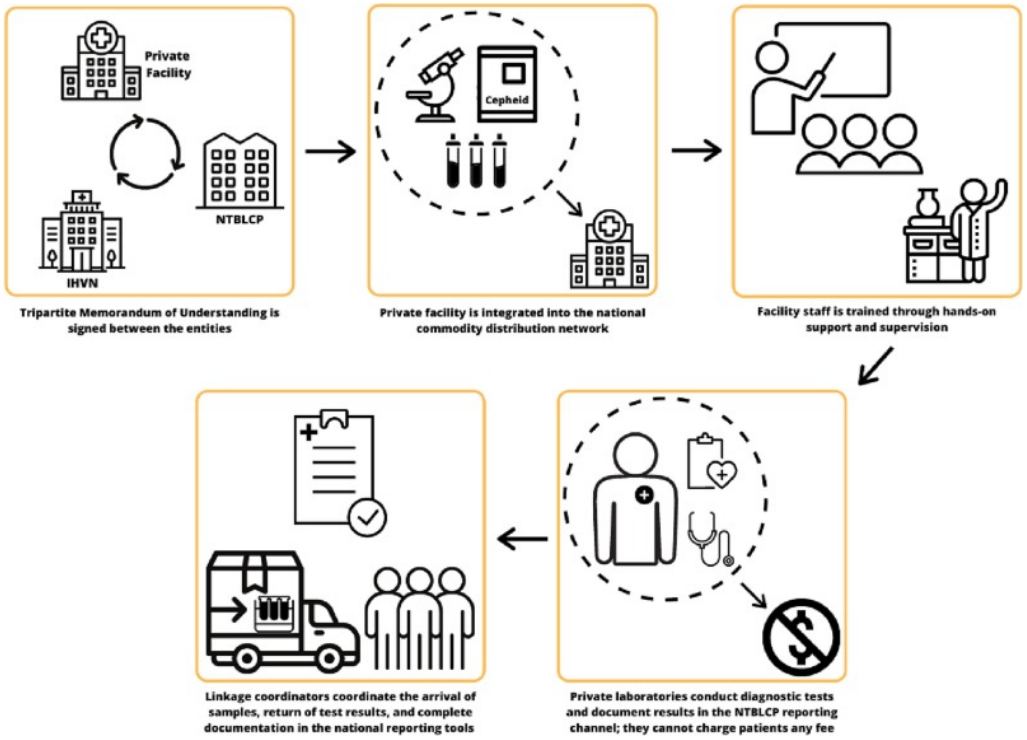

Figure 4: PPM Hub-and-Spoke Model for Nigeria *(Image source: Taofeekat Ali et al*[15]*, 2023)*

Note: Hubs = private laboratories with GeneXpert capacity (standalone, hospital-based, FBOs, PFPs); Spokes = community pharmacists, patent medicine vendors, traditional birth attendants/healers, independent diagnostic laboratories.

As communicated by NTBLCP during the country validation workshop, the strategy for expanding access to testing services and achieve the targets of the End TB strategy is based on the "potential to meet the need" for rapid TB diagnostics in the country as per below details:

The target for access to mWRDs is set as 1 per 175,000 population.
The status as of October 2025 is 1,162 mWRDs which have been deployed (including.: 513 GeneXperts, 277 TB-LAMP & 372 Truenat)

Accordingly, there remains a gap of 200 mWRDs (based on a population estimate of 230 million) to be positioned at PHC level & in hard-to-reach areas.

These priorities suggest value for accelerating market entry and uptake of near POC portable oral swab-based rapid molecular tests or next generation LAM tests in Nigeria, and the country has been selected by the Global Fund as one of the 13 candidates early implementers for the PlusLife MiniDock MTB test for the **NPOC access fund** under a next generation market shaping strategic initiative aiming to accelerate roll out of new tools and address the estimated shortfall needed to meet WHO target for universal access to mWRDs testing.

National regulation of medical devices and in vitro diagnostics (IVDs)

Several regulatory bodies have been set up by the government of Nigeria to regulate and control products (either locally manufactured or imported) upon entry in the national market to ensure that quality and safety standards are met, as listed:

- The National Agency for Food and Drug Administration and Control (NAFDAC), established by Decree No. 15 of October 1993, amended by the ACT Cap N.1 LFN 2004[17], has a mandate which encompasses the regulation and control of the manufacture, importation, exportation, distribution, advertisement, sale and use of regulated products in the country, including: Food, Drugs, Cosmetics, Medical Devices, Packaged Water, Chemicals and Detergents. Medical devices are overseen by the Director, at the Vaccines, Biologics and Medical Devices Registration & Regulatory Affairs (VBM-R&R) Directorate. NAFDAC is one of only nine national regulatory authorities on the African continent which have achieved maturity level 3 (for medicines and vaccines since 2022) on the WHO global benchmarking tool (GBT)[18], indicative of "stable, well-functioning and integrated regulatory systems" and was the first one globally to undergo benchmarking under the new GBT plus Medical Devices in November 2024[19].

- The Medical Laboratory Science Council of Nigeria (MLSCN), a Federal Government Statutory Regulatory Agency established by Act 11 of 2003, has a mandate that includes regulation of the production, importation, sales and stocking of diagnostic laboratory reagents and chemicals as stipulated in MLSCN IVDs regulations[20].

- The Standards Organization of Nigeria (SON) established by an Enabling Act Number 56 of December 1971 and amended by the Act Number 91 of June 2015[21], has the mandate to designate, establish and approve standards in respect of metrology, materials, commodities, structures and processes for the certification of products in commerce and industry throughout Nigeria. Under this mandate, SON is responsible for establishing import and export product surveillance, as well as a mandatory conformity assessment program for locally manufactured products in Nigeria. Specifically, SON manages:
    - The mandatory Offshore Conformity Assessment Program (SONCAP), a pre-shipment verification of conformity to Standards, approved equivalents, and technical regulations before
    - The Mandatory Conformity Assessment Program (MANCAP) for locally manufactured products.
    - The Products Registration Program

[17] Official Gazette, no 131, June 2015. NAFDAC ACT Cap N.1 LFN 2004. Federal Republic of Nigeria. 2021. Accessed 5 Jan 2026.
[18] List of NRAs operating at ML3 & ML4. WHO. Accessed 5 Jan 2026.
[19] Presentation on the Regulation of Medical Devices. 5th WHO Global Forum on Medical Devices. 3rd June 2025. Accessed 5 Jan 2026.
[20] IVDs regulations 2021, Federal Republic of Nigeria Official Gazette, no 123 of 28th July 2021. Accessed 10 Nov 2025.
[21] Official Gazette, no 91, June 2015. Federal Republic of Nigeria. 2015.

More details about NAFDAC, MLSCN and SON, their mandates and operations and how these unfold along the critical pathway for the introduction of new TB diagnostic tools are presented in the *Overview of the principal steps along the critical pathway* part of this report, specifically under the *Regulatory requirements for the introduction of new TB diagnostics at country level* and the *Procurement and supply chain* sections of this report (pages 18 and 27).

Methodology

This critical pathway analysis was led by Matahari, funded by the Gates foundation with McGill University School of Population and Global Health coordinating the project across the African and South/ Southeast Asian regions.

The CPA methodology involved a blended approach involving a desk review, virtual and face-to-face outreach, and consultations with key stakeholders focusing on the following nine thematic areas:

a) *Regulatory approval at the global and continental level (including WHO and Africa Union)*
b) *Regulatory approval at country level*
c) *Validation, review of evidence and inclusion into policy by national TB program or MoH*
d) *Product use cases*
e) *Advocacy and demand creation*
f) *Early adoption and roll out: health systems & implementation needs*
g) *Health insurance & pricing*
h) *Supply chain and procurement*
i) *Scale up: network improvement/optimization and M&E*

An operational protocol was developed for a thorough desk review of documents (including file name or link, type of source, and date of publication where available) collected through a combination of systematic online searches and engagement with country stakeholders. These were categorized in a repository to enable triangulation of insights consistent with the nine thematic areas above and organized as follows:

a) *Private Public Mix Documents*
b) *Partners Documents*
c) *NTLP Documents*
d) *NRA Documents*
e) *Other MOH Documents*
f) *Lab Network Documents*,
g) *Algorithms, Guidelines, and SOPs*

The analysis involved four distinct stages:

Phase I (Inception):

An initial virtual engagement meeting was held with Nigeria NTBLCP on 15th September 2025, to obtain initial endorsement of the project and map key country stakeholders (see figure 5 and Annex III).

Phase II (Data collection and analysis):

A standardised questionnaire encompassing the 9 thematic areas of interest was developed and piloted with Treatment Action Group (TAG), Stop TB Partnership, Diagnostic Equity Consortium (DEC) and Médecins Sans Frontieres (MSF) Access Campaign. This questionnaire guided a desk review of the repository using DocAnalyser.ai, a document parsing and data extraction software. The same was also used to guide the consultative process with stakeholders during the in-country validation workshop.

Phase III (Sensemaking and validation):

A country consultation and validation workshop took place on the 27th-28th October 2025 in Abuja, Nigeria involving key stakeholders identified during the inception phase (see attendance list Annex III). The consultation was guided by the completion of the standardised questionnaire (based on consensus of the participants) and breaking group discussions on qualitative elements such as pricing levels attractive for NTPs, anticipated barriers in the national regulatory and policy processes, **criteria informing the choice of new tools/placement/use within the existing network**, and possible strategies to shorten pathways and maximize uptake. Insights from the consultation inform the development of roadmaps (see figures 11 and 12) using Microsoft Office Visio diagramming and flowcharting software, mapping out the critical steps, key stakeholders and decision points involved along the pathway for the introduction of new TB diagnostic tools in Nigeria, with hyperlinks provided to guiding documents.

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 for the introduction of the new tools. Dissemination shall occur through different fora at the country level such us Witwatersrand University Advanced Diagnostic Course in South Africa, as well as at regional and international fora including McGill University School of Population and Global Health summer global health courses, the TB Union world conference, debriefing to technical agencies and partners (WHO Global TB program (GTB) and WHO Prequalification Unit (PQ), the Global Fund, UNITAID, Africa CDC etc..) and via peer review publications with prior approval/endorsement from the country NTLP.

Findings

Overview of Nigeria key stakeholders' roles and responsibilities along the critical pathway

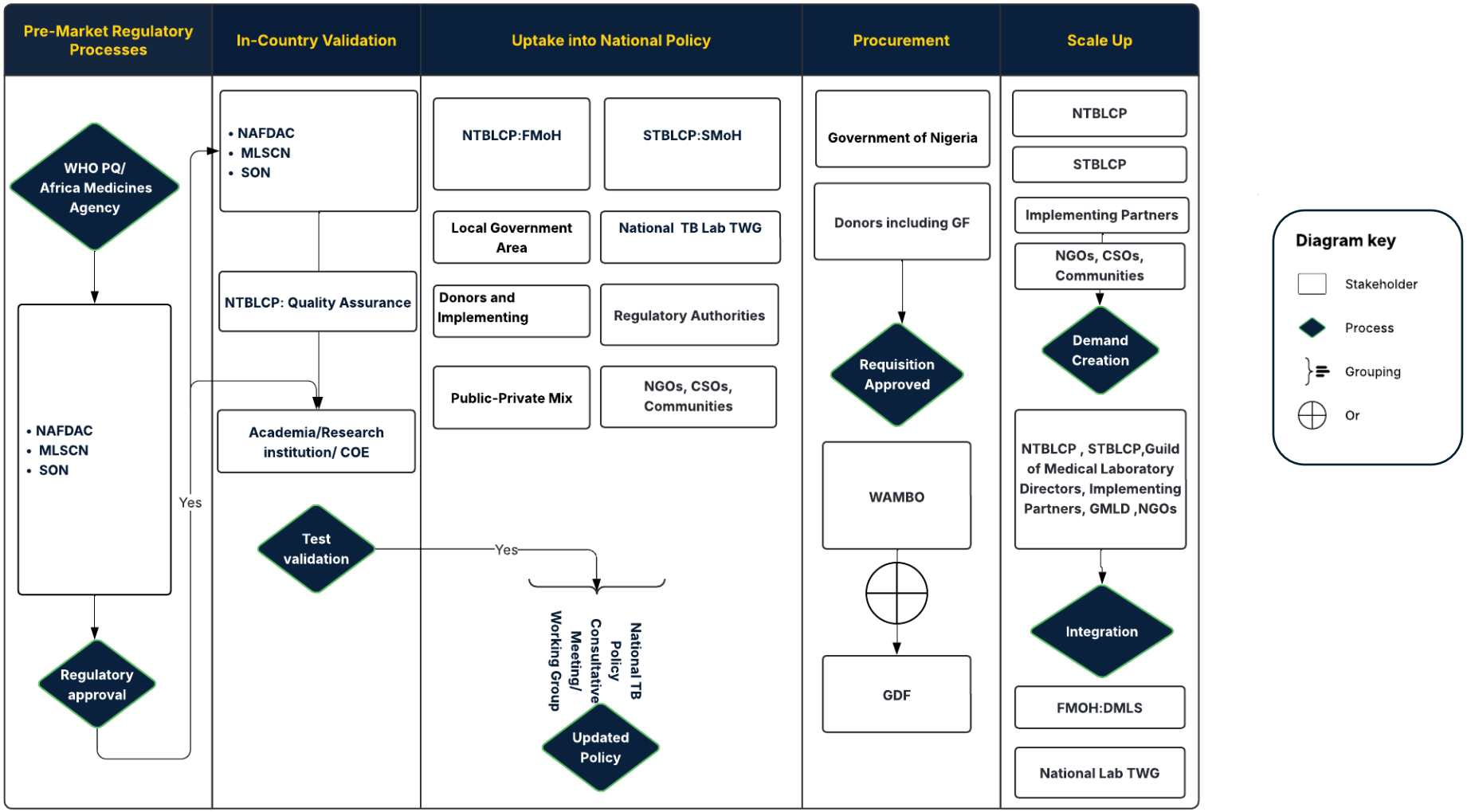

Figure 5: Map of key stakeholders along the new diagnostics introduction pathway in Nigeria

Overview of the principal steps along the critical pathway, including enablers, challenges and anticipated timelines

Outcomes of the desk review and of the face-to-face validation workshop held in Abuja on the 27th and 28th October 2025, are presented below, including highlights about key stakeholders, steps and processes along the pathway for the introduction of new diagnostic tools in Nigeria.

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	At the global level, **listing by the WHO PQ unit** or **policy recommendation by the WHO GTB Guidelines Development Group (GDG),** will facilitate and streamline the approval process for new TB diagnostics in Nigeria either through NAFDAC WHO collaborative review procedure[22] or via an MLSCN MoU with WHO PQ team[23]. At the continental level, the operationalization of the **Africa Medical Agency (AMA)** and the appointment of its Director General [24] in March 2025, has accelerated initiatives focused on strengthening the regulatory framework for medical devices and IVDs spearheaded by **Africa CDC and the African Medical Regulatory Harmonization program** (AMRH, precursor to the AMA), including the piloting of a continental joint review and listing process for IVDs for outbreak prone diseases in the context of the Mpox public health emergency of international concern. Furthermore, under the helm of the West Africa Health Organization (WAHO), the **West Africa Medicines Regulatory Harmonization Project (WA-MRH)**[25] was executed between 2017 and 2020 to facilitate the joint assessment and registration (single process) of medicines and other medical products in the 15 Economic Community of West African States (ECOWAS) Member States.
Enablers	▪ **Availability of WHO GTB policy recommendations or WHO PQ listing**. ▪ In 2019, the **WAHO WA-MRH project** piloted the regional single process for registration of TB products (medicines)[26], which sets a precedent that could potentially be leveraged for TB diagnostic tools. ▪ Though Nigeria has not yet ratified the AMA Treaty, the country has contextualized the AU model law aimed at harmonizing medical products regulatory systems in Africa[27], hosts regional centers of excellence (see Annex II) and has been party to AMRH technical working groups[28].The country would therefore plausibly take up recommendations issued through a potential **continental joint review and listing procedure** for TB medical devices and IVDs.
Anticipated barriers	▪ Potential overlaps between global, continental, regional regulatory harmonization initiatives and country level processes vs limited local capacity and expertise to handle all product categories, including diagnostics, which may lead to delays rather than to anticipated synergies[29]. ▪ The limited scope of the AMA/AMRH and Africa CDC led joint continental review and listing procedure which includes currently diagnostics for outbreak prone priority diseases but not yet TB diagnostics.

[22] Guidelines for Registration of Medical Devices Including In Vitro Diagnostics Under WHO Collaborative Registration Procedure. NAFDAC, April 2025. Accessed 10 Nov 2025.
[23] Communication from Paulinus Offutalu, MLSCN representative to the country validation workshop.
[24] Press release : Dr. Delese Mimi Darko Appointed Inaugural Director General of the African Medicines Agency (AMA). Africa Union, June 2025. Accessed 2 July 2025.
[25] Project summary: WA-MRH. WAHO. Accessed 6 Jan 2026.
[26] Call for expression of interest (EOI) for regional joint medical products evaluation for antituberculosis medicines. WAHO, 2019. Accessed 6 Jan 2026.
[27] Country overview: Nigeria. AMRH. Accessed 6 Jan 2026.
[28] 5 Year Workplan for AMRH Support to Operationalization of the AMA. 2022-2026. AMRH, 2022. Accessed 6 Jan 2026.
[29] Wairagkar N et al. The Afican Medicines Agency - A potential gamechanger that requires strategic focus. *PLOS Glob Public Health*. Feb 2024

Timelines for obtaining regulatory approval	Via WHO GTB or WHO PQ program: • variable depending on review cycle and availability of evidence. Notably, WHO GTB recently announced the convening of its Guideline Development Group (GDG) to evaluate the quality evidence on the use of new near POC tests and tongue swabs as an alternative sample type for the initial diagnosis of TB, with the publication of related WHO recommendations expected beginning of 2026. • PQ from **270-to 350 days (full PQ assessment)** to **100-180 days (abridged PQ assessment)** • Subsequent marketing authorization certificate to be granted within **90 days through NAFDAC collaborative registration** procedure or **MLSCN/WHO PQ MoU**. Via the WA-MRH • The timeline for review is not specified, however obtention of approval confers the product with **eligibility for inclusion in the products register of each NRA in all 15 ECOWAS Member States** upon payment of the applicable registration fee (application to be made within a delay of 2 years after approval)[26]. Via the AMA/Africa CDC joint continental review and listing (**during public health emergencies of continental security such as i.e.: Mpox**): • **15-45 days** for joint dossier review and issue of recommendation following manufacturing site inspection (duration variable). • Subsequent registration at country level **within 90 days**.

Regulatory requirements for the introduction of new TB diagnostics at country level	
Overview of key steps, tasks and parties involved	According to the domestic legislation[30], multiple pathways exist for the registration of (laboratory) medical devices and IVDs. **1) NAFDAC pathway** **Routine registration:** Key steps, as described in the corresponding NAFDAC guideline[3132], include: • Online application on NAPAMS, NAFDAC automated product registration system. • Documentation screening, inclusive of technical dossier compliance with the International Medical Devices Regulators Forum (IMDRF) table of content (ToC) and following specific formatting, **language (English)**, file, and naming conventions. • Declaration of conformity proportional to device risk (Class A, B, C or D) and Quality Management System (QMS) Compliance (i.e. ISO 13485) • Import permit issuance for registration samples (for imported devices) • GMP inspection of the manufacturing site (local and foreign) • Submission/drawing of samples and NAFDAC laboratory analysis (as applicable) • Presentation to the Food and Drug Registration Committee (FDRC) for approval. • Successful application leads to the issuance of a **5-year Certificate of Registration (renewable)** • Registration costs and other ancillary fees are listed on NAFDAC website. **Non routine, expedited registration:** NAFDAC may issue a time-limited listing authorization for unlicensed products under its Emergency Use Authorization (EUA) guideline[33]. As stipulated, the EUA is reserved for "*vaccines, therapeutics, and IVDs in the event of a PHE … given the morbidity and/or mortality of the disease and the lack or paucity of treatment, diagnosis/detection or prevention options*" **according to specific criteria (for IVDs: 1) unmet need, 2) production under a functional QMS and 3) commitment from manufacturer to complete validation and verification of the product in the case of IVDs and apply for licensure**. Notwithstanding, and as stated (page 5), an IVD that does not fully meet those requirements could still be reviewed if the application is supported by a letter of justification. **Variations to a registered product:** Changes to a previously registered medical device, including IVDs, that affect, inter-alia, its intended purpose and/or indication of use or its performance, require the market authorization holder to notify NAFDAC for evaluation and approval or to apply for a new registration as detailed in the corresponding guideline[34].

[30] Relevant domestic legislation states that the Medical Laboratory Science Council of Nigeria (CAP M25 LFN., 2004) In-Vitro Diagnostics Regulations is to "evaluate or validate equipment, reagents and consumables used in IVDs laboratory (sic) in Nigeria". (Regulation 1(g)) and that the Council "shall be the regulatory authority for IVDs activities in Nigeria" (Regulation 4(1). The Gazette further describes that these activities shall include, inter alia, post-market surveillance and certification of all IVDs entering the Nigerian market. (Regulation 4(2)(l)) The National Agency for Food and Drug Administration and Control Act Cap N.1 LFN 2004, meanwhile, states that NAFDAC shall "undertake the registration of food, drugs, cosmetics, **medical devices**, bottled water and chemicals". (Section 5(f)). While the NAFDAC Act does not define 'medical devices', the definition can be found in the Food, Drugs and Related Products (Registration, etc.) Act (Cap F33 LFN 2004), which defines the term "medical device" as: "*any instrument*, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external *use in the diagnosis*, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof in man or animal." (Emphasis added). The NAFDAC Act therefore confers broader powers over 'any instrument' used for diagnosis. As such, based on the analysis, the laws are duplicative and create parallel systems.

[31] Guidelines for Registration of Medical Devices in Nigeria, NAFDAC, November 2024.

[32] Guidelines for Conformity Assessment of IVD Medical Devices, NAFDAC, November 2024.

[33] Guidance on Emergency Use Authorization for Medical Products, NAFDAc, Oct 2024.

[34] Guidelines on Variations To Registered Medical Devices including IVDs & Related Products, NAFDAC, November 2024.

	2) MLSCN pathway MLSCN is responsible for issuing IVD product certificates to ensure that only quality IVDs enter the Nigerian market[30] (either locally produced or imported). Requirements for registration of an IVD product or listing of an equipment, including related costs, are detailed on the council website and in MLSCN Laboratory Handbook[35]. Guidelines and forms for manufacturers as well as listings of approved IVD products and approved IVD providers are also accessible. Specifically, • Domestic manufacturers as well as importers of IVD equipment, reagents and consumables must register on the Council electronic portal within 45 days of commencing business and renew annually. • Both domestic and imported products require conformity assessment, product evaluation, compliant labelling/IFUs/**language (English)**, listing, and are subject to post-market surveillance and withdrawals. Foreign-based manufacturers can only be registered through a local agent. • Domestic manufacturers and importers cannot produce or import, respectively, IVDs with less than 2 years expiry unless expressly approved by the council. • Upon successful application, issuance of a **product certificate which is valid for 5 years**. According to a regional report[36], NRAs' operations (e.g.: support for office operations, guideline production, utilities, capacity building, equipment, and laboratory activities) are funded by a mix of government subventions, industry fees, and donor support (e.g., UNFPA, WHO, EU, etc.). NAFDAC website indicates that funding for the agency activities is majorly drawn from the Federal Government of Nigeria, with internally generated revenues (user fees) and other external sources (donor agencies) providing funds in some circumstances.
Enablers	• NAFDAC's participation in the WHO NRA benchmarking program and specifically its leadership as the first pilot country for the new **WHO GBT plus medical devices benchmarking** in November 2024 with 2 additional (self) benchmarking in August and October 2025. • On 26th November 2025, NAFDAC has officially been admitted into **full membership of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)**, attesting Nigeria's commitment to strengthen its regulatory ecosystem and support local pharmaceutical innovation and manufacturing[37]. • As noted in the country consultative workshop, the Directorate of Laboratory Services is engaging in **high-level discussions with the FMoH to ensure better coordination between IVDs regulatory pathways**. This effort is expected to make the application process easier for manufacturers.
Anticipated barriers	• Manufacturers often face **confusion and uncertainty** about where to submit new IVD registration applications **due to the existence of multiple approval pathways** for medical devices and IVDs
Timelines	NAFDAC pathway (from acceptance of submission to issuance of registration number): • Regular registration: **120 working days (class A)** or **240 days (class B, C, D)**. • WHO collaborative registration procedure: **60 working days** (additional to **30 working days** for WHO PQ team to provide NAFDAC with product related information & documentation) • Expedited review under EUA: **14 working days**. MLSCN pathway: • Company registration (initial/renewal): within **1 month** • Product validation and listing: within **4 months**. • Equipment listing: within **4 months**. • WHO pre-qualified products (in country verification only): within **90 days**.

[35] Laboratory handbook, MLSCN Public health IVDs control laboratory (MLSCN/IVD/HB/196 V-002) MLSCN (date not specified). Accessed 6th Jan 2026.
[36] Kamwanja LA *et al*. Situation analysis study on medicines registration harmonisation in Africa for the Economic Community of West African States (ECOWAS) . June 2011 (page 26)
[37] Press release : NAFDAC Announces a transition from an Observer Status to Full Membership of ICH.NAFDAC, 5Dec 2025. Accessed 6.Jan 2025.

Validation, review of evidence and inclusion into policy by national TB program, including use cases	

Overview of key steps, tasks and parties involved	**Validation studies:**
	
	Based on the recent experience for the introduction and uptake of new TB diagnostic tools (e.g.: the Truenat and TB LAMP assays[38,39]) in Nigeria, the following evidence is required for inclusion of a new diagnostic tool into policy and subsequent uptake and scale up:
	
	• **Pre-market validation:**
	  ○ **MLSCN conducts in-country pre-market validation/verification (PMV)** of new diagnostic tools via its Public Health IVDs Control Laboratory validation/verification under Nigeria National Accreditation System (NiNAS) ISO/IEC 17025:2017-accredited quality management system (MLSCN Public Health IVDs control laboratory handbook, page 6). According to the scope of the ISO certificate and a public notice published by MLSCN in 2022[40], this process specifically encompasses rapid tests for HIV, malaria, COVID19, Hepatitis B and C. **Moreover, Nigeria National Essential Diagnostics List (NEDL)[41] mostly refers to WHO recommendations/PQ as supporting evidence for TB IVDs to be used across the national lab network, it accordingly appears that TB IVDs are not yet fully incorporated under this validation process**.
	• **Post-market validation:**
	  ○ The NTBLCP coordinates post market verification through the **National Quality Assurance (QA) Team**, assessing laboratory performance characteristics of incoming kit lots before deployment.
	• **Continuous quality assurance** during deployment and scale up of new diagnostic tools:
	  ○ The National Reference Laboratory validates and evaluates diagnostic protocols, prepares EQA panels, and provides technical assistance.
	  ○ Zonal and State TB Reference Laboratories support oversight, panel distribution, and supervision
	  ○ EQA performance is monitored through biannual panel testing and quarterly on-site evaluations, with required corrective actions if performance falls below thresholds.
	
	Evidence is also generated by academic institutions and technical partners, either upstream or downstream of the regulatory approval process (see Annex IV for a detailed overview) with pilot introduction / operational research studies undertaken to refine implementation strategies and planning (i.e. Stop TB Partnership introducing new tools project for the Truenat system)[42].
	
	Review of evidence and inclusion into national policy:
	
	Nigeria NTBLCP, under the oversight of the FMoH and the Department of Public Health, and in coordination with State TB Programs and national reference laboratories, leads the review of evidence and decision-making on new diagnostic tools for inclusion into national policy, working through various technical working groups (e.g.: the TB Laboratory Technical Working Group (TB LWG), the National Laboratory Technical Working Group (NLTWG), PMDT committee etc.)[11,41]. Specifically, NTBLCP convenes stakeholders on a quarterly basis, develops policy documents and ensures their dissemination and implementation.
	
	As per documentation reviewed, critical partners involved in the review and decision-making process, include, among others:
	
	• NAFDAC and MLSCN (regulatory approval and product validation)
	• WHO country office
	• Global Fund, USAID and CDC/PEPFAR (funding)

[38] National Guidelines for the Implementation of Truenat test for the Dectection of TB and Resistance. FMoH/NTBLCP. June 2021
[39] National Guidelines for the Implementation of TB-LAMP test for the Diagnosis of TB. FMoH/NTBLCP. June 2021
[40] Public notice. MLSCN. 24th Aug 2022. Accessed 6 Jan 2025.
[41] Nigeria National Essential Diagnostics List. FMoH. May 2022
[42] Factsheet: Transforming Access to TB Diagnosis with Truenat in Peripheral Facilities in Nigeria.Stop TB Partnership. April 2024. Accessed 6 Jan 2025.

- Local and international technical/implementing partners (e.g., IHVN, KNCV Nigeria and KNCV international, CHAI, MSH, Damien Foundation etc.)
- Civil society/Community based organizations (see details under the D*emand creation* section of this report)
- Academic institutions (operational research and validation, i.e., Johns Hopkins University/SMART4TB consortium partners, see details under Annex IV)

Nigeria TB NSP 2021-2026 specifies that the **policy and guideline revisions are planned and tied to scheduled expert reviews, meetings and printing cycles** (e.g., diagnostic algorithm reviews every two years, guideline updates and printing in specified years).

Potential use cases:

1) **Near POC (swab based) rapid molecular test**

Based on the current priorities of the NTBLCP[11], and as confirmed during country validation workshop, anticipated use cases for a near POC/POC swab based rapid molecular test would include the following:

- **complement/replace other molecular WRDs** for rapid case detection (including capacity for DTS as applicable) to expand coverage an access nationally, notably at decentralized healthcare level.
- **support active case-finding initiatives** among key affected populations and/or in high-risk settings (e.g. outreach in communities, prisons, miners, high-risk groups/PLHIV/contact case investigations)

2) **Next generation TB LAM test**

Urinary LF-LAM test is currently recommended for use as a screening test only in people living with HIV (PLHIV) with advanced disease or seriously ill[43]

- A next generation LF-LAM that could be used irrespective of HIV status could **allow to expand the use of the test**, especially for active case finding at primary health care /ART sites (TB NSP 2021-2025) and **among children and hard to reach populations**.

Prioritisation criteria for new TB rapid diagnostic tools

The upcoming WHO GDG recommendations on near POC TB tests compatible with swab samples may enable the approval and adoption of many diagnostic tools from the same class in the coming years. To determine what strategy the NTBLCP would adopt in such circumstances (multiplicity of diagnostic assays and platforms to choose from) a dedicated discussion was held during the country validation workshop to identify about prioritisation criteria that could inform the NTBCLP decision making process, with the following highlighted by the assembly:

[43] National Guidelines for the Management of TB/HIV Co-infection in Nigeria (page 12 and 84). 2021

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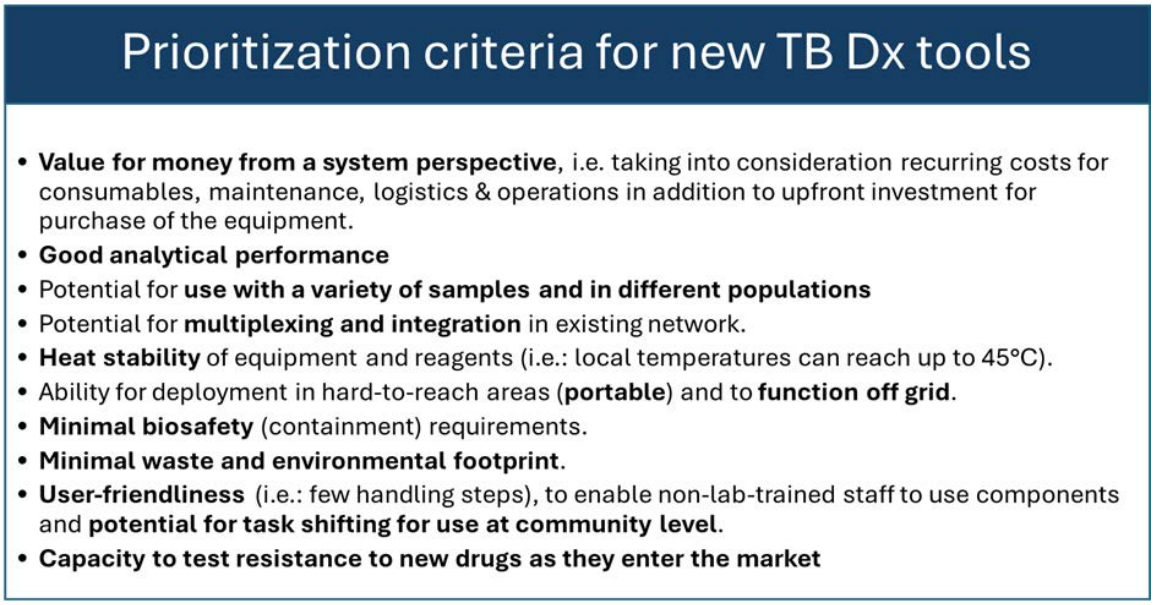

Figure 6: Prioritization criteria for selection of new TB diagnostic tools in Nigeria

Quote from NTBLCP Director:

"The ideal tool would fit in my pocket and allow me to provide testing services to anyone where and when needed"
</td></tr>
<tr><td>Enablers</td><td>
• Established frameworks and guidelines for the validation of IVDs both at MLSCN and NTBLCP level.
• Good coordination and collaboration with in-country partners (e.g. IHVN, KNCV Nigeria), academia/research centers (e.g. Zankli Research Center) and civil society (e.g. Jana Health Foundation) to conduct operational and implementation studies to inform NTBLCP strategies and operational planning.
• Availability of an NEDL[41] to inform placement of new TB diagnostic tools across the tiers of the lab network and guide integration into TB diagnostic algorithms.
• NSP[11] stated openness to innovation and objectives to adopt new tool to increase access and coverage in decentralized settings.
</td></tr>
<tr><td>Anticipated barriers</td><td>
• Potential for overlap between MLSCN and NTBLCP QA team led post market validation and need for coordination.
</td></tr>
<tr><td>Timelines</td><td>Based on historical data for the introduction of the Truenat assay (see figure 13), a timeline of 1 year was required between WHO endorsement and inclusion into national TB program policy.</td></tr>
</table>

Advocacy and demand creation

Overview of key steps, tasks and parties involved

As presented in the section on "*Considerations on the current TB funding landscape*" of this report, page 33, Nigeria is facing a 73% gap for financing TB control activities in the country, compounded by a very low share of domestic funding. To strengthen domestic resource mobilisation, the NTBLCP benefits from high profile support from the first Lady of Nigeria and the First Ladies of the various states, acting as Ambassadors for TB, and leverages wider health sector program such as the **Saving One Million Lives Initiative**[44].

Based on discussions during the country consultation meeting, key stakeholders for advocacy and demand creation can be divided into national and subnational levels as follows:

	Stakeholders	Activities
National	**Government Bodies** | NTBLCP, NASCP, NACA, NCDC, NPHCDA, Stop TB Partnership, Implementing Partners (KNCV, IHVN), Office of the First Lady	Established outreach days - World TB Day, World AIDS Day, National Testing Week, RMNCH week, etc. Press Releases, Briefings, Field Activities
	Professional Bodies | GMLD, AMLSN, PCN, NMA, Nurses Association, National Association of Community Health Practitioners	Conferences, Trainings, Workshops, Exhibitions – Sessions to discuss New Technologies and impact for the TB response
	Regulatory Bodies | MLSCN, NAFDAC, SON	Press Releases, Briefings, Field Activities
	Social Mobilisation Bodies | NOA, Media, CBOs, NGOs, FBOs, Network of TB Survivors (TB People), Network of People Living with HIV (NEPWHAN)	Press Releases, media roundtables, Dedicated health programmes on Radio/ TV, Social Media Campaigns
Subnational	**Leadership** | Traditional Rulers, Community Chiefs, Religious Leaders	Health Awareness Creation programmes (To demystify prevailing myths and misconceptions), inclusion of messages encouraging testing in faith-based leaders in their sermons
	State TB Champions | Wives of Governors/ Local Govt Chairmen 's wives), STBLCPs, SACAs, SASCPs, SPHCDA, CBOs, TB People, NEPWHAN	Outreach during - Maternal and Child Health Week, World TB Day, Childhood Testing Week, World AIDS Day, World Hepatitis Day & Other notable days that can support integrated testing
	Service Providers | National NGOs, PMVs, Standalone Private Labs, Health Facilities	Antenatal services, OPD Clinics, Routine Immunisation Services, Community Sensitisation sessions, Household visits, Contact Tracing
	Health Workers | Community Health Extension Workers, Lab technicians (private labs)	Community outreaches

[44] Adewole I & Adeyi O. Saving one million lives programme for results and implementation in Nigeria: A report. *African Journal of Reproductive Health* November 2022

Enablers	Different modalities will enable NTLBCP to create demand around new tools with representative examples provided below: • **Involvement of Private Sector providers, CBOs, NGOs in supporting service delivery and demand creation in hard-to-reach locations/populations**, facilitated by previous and current support from donors and partners, as well as key professional bodies, such as Guild of Medical Laboratory Directors (GMLD)- an umbrella body for private stand-alone laboratories in Nigeria; Association of Community Pharmacist of Nigeria (ACPN)- an umbrella body for pharmacists in private practice, Patent and Proprietary Medicine Vendors Association of Nigeria (PPMVAN)- representing vendors who sell OTC medicines, often serving as a key access point for basic healthcare in communities, Health Federation of Nigeria (HFN)- a coalition advocating for private healthcare sector improvements, and the Association of Nigerian Private Medical Practitioners (ANPMP) for doctors in private practice who may or may not own private clinics in Nigeria. • **Communication in local languages:** The country has a nomadic population that is at higher risk of TB, due to poverty, social exclusion, and lower access to health services. A study conducted by Janna Foundation showed that information about TB was primarily received through radio in their local language Fulfulde, then through community members and school.[45] • **Political support from the 1st Lady as a TB Ambassador (Funding for the TB response) as well as Investiture of Governors' Wives as TB Champions** • **Media support and health promotion** of new diagnostics at the National, subnational and community levels • **NTBLCP early involvement in international or regional platforms (i.e.: TB Union Conference, ASLM Laboratory Community of Practice)** to disseminate lessons learnt from pilot introduction of new tools and strategies for TB testing services expansion[46]
Barriers	Anticipated barriers to demand creation for new TB diagnostics include: • Superstitious beliefs, myths and misconceptions, fear of discrimination • Attrition of trained personnel • Limited awareness/Negative Mindset/Resistance to change for uptake of newer diagnostics • Low domestic funding caused by, inter alia, a lack of targeted and effective advocacy to relevant government authorities and corporate organisations[11] • Declining funding from Global Fund and other key partners and limited funding (for outreach activities, training, infrastructure upgrade etc) • Security challenges and population displacement in Northern regions • Limited media and health promotion interventions
Timelines	Advocacy and demand creation is an ongoing process.

[45] John S, et al. Using a Knowledge and Awareness Survey to Engage and Inform a Community-Based Tuberculosis Intervention among Nomads in Adamawa State, Nigeria. *Tropical Medicine and Infectious Disease*. 2024

[46] Experience sharing on Truenat implementation in Nigeria at TB CAPT symposium during ASLM LabCoP meeting, October 2022 (at 1hr 02 timestamp)

Health Insurance, pricing & financing

Overview of key steps, tasks and parties involved

Health insurance:

The National Health Insurance Authority Act of 2022 establishes the National Health Insurance Authority (NHIA) to promote, regulate and integrate health insurance schemes in Nigeria. The NHIA act makes social health insurance mandatory for all residents of the country and requires States to establish and implement States social health insurance schemes. The National Health Insurance Act mandates enrolment and expressly includes private health insurance schemes.

As part of the strategic interventions of the TB NSP[11], the NTBLCP has planned to perform actuarial analyses to determine the cost of including TB services in the National Health Insurance Scheme (NHIS), to support the elaboration of the new NHIS guidelines and is actively promoting the inclusion of all elements of TB care into insurance scheme benefit packages (national and state level).

The presidential executive order of September 12th 2025, re-emphasized the mandatory nature of NHIA, aiming at expanding coverage across all sectors nationwide and at "providing access to affordable and quality healthcare while significantly reducing out of pocket expenditure on health".

Figure 7: NHIA benefits package (*Source: NHIA website*)

	Financing (other domestic sources): The **Basic Healthcare Provision Fund (BHCPF)**, established by the National Health Act (2014), is a mechanism which seeks to fund a Basic Minimum Package of Health Services and therefore increase the fiscal space for health. Nigeria plans to raise BHCPF funding from 1% to 2% of revenue.[47] As part of the strategic interventions of the TB NSP, the NTBLCP aims to ensure TB services are included in BHCPF. **Pricing:** Nigeria qualifies for **concessional pricing through mechanisms supported by the Global Fund / Stop TB Partnership/Global Access Program**. NTBLCP and its partners accordingly purchase tests at negotiated prices[48] to which needs to be added a surcharge that reflects real-world procurement and operational costs (e.g. USD 11.33 vs USD 7.97 for the Xpert MTB/RIF Ultra cartridge[49] The WHO GDG is expected to recommend a new class of rapid, near POC TB molecular diagnostic tools in early 2026. One example from this class, the PlusLife MiniDock MTB test, has already received procurement approval from the WHO/Global Fund Expert Review Panel for Diagnostics (ERPD) and was recently added to the Global Drug Facility (GDF) catalog as follows: • Test: USD 3.60 • Thermolyser: USD 155 • MiniDock Ultra device: USD 180.
Enablers	• **Financial support by Global Fund under grant cycle 7 for expansion of the NHIS** in five states: Kwara, Gombe, Ebonyi, Anambra, and Lagos would expand access for selected populations of vulnerable people living with TB.[50] It is expected that lessons learnt from this pilot will inform nationwide scale up. • **Country eligibility for the Global Fund Market NPOC Access Fund** for early implementation of the PlusLife MiniDock MTB test, providing the country with early access during grant cycle 7 at an all inclusive (freight, in country logistics, installation and training) price of USD 7.04 per test and to potentially achieve scale up during grant cycle 8.
Anticipated barriers	• According to a recent paper examining implementation challenges, despite the existence of the NHIS, many Nigerians still face **high out-of-pocket expenses** for healthcare. Furthermore, the **NHIS has a low enrolment rate, with only about 5% of Nigerians enrolled**.[51] [52] [53] Likewise, state contributory health insurance schemes face variations in uptake largely due to a lack of awareness and financial barriers.[54]
Timelines	Pilot roll out of the MiniDock MTB test under the NPOC access Fund is expected to take place **in 2026**.

[47] Vivek Panwar, 'Nigeria seeks increase in Basic Healthcare Provision Fund' P4H Social Health Protection Network, 3 Sept 2025. Accessed 8 January 2026
[48] Diagnostics, Medical Devices and Other Health Products Catalog. GDF, Dec 2025. . Accessed 12 January 2026
[49] Ibrahim HU et al. Cost-effectiveness of different tuberculosis diagnostic approaches in Nigeria based on decision analytical modelling. *BMJ Global Health*. 2025.
[50] James Emejo, " NHIA, States Move to Maximise $669m Global Fund Support for Health Insurance" Arise News, 5th Nov 2024. accessed 9 January 2026
[51] Eze OI et al. The National Health Insurance Scheme (NHIS) in Nigeria: current issues and implementation challenges. *Journal of Global Health Economics and Policy.* 2024.
[52] Nigeria National Essential Diagnostics List. FMoH. May 2022
[53] Nwanaji-Enwerem, O et al. Patient satisfaction with the Nigerian National Health Insurance Scheme two decades since establishment: A systematic review and recommendations for improvement. *African Journal of Primary Health Care & Family Medicine*, 2022.
[54] Effiong, F. B., et al. Coverage and predictors of enrollment in the state-supported health insurance schemes in Nigeria: a quantitative multi-site study. *BMC public health*, 2025.

Procurement and supply chain

Overview of key steps, tasks and parties involved

As per information provided at the time of the country consultation, **~90% of TB lab instruments and commodities were financed through the Global Fund grant** and procured through Global Fund supported mechanisms (i.e. Stop TB partnership **GDF or Wambo**) and provided free of charge to all TB patients. TB diagnostic products are distributed via national/state stores and through third-party logistics.

The NTBLCP Procurement and Supply Chain (PSM) management team leads the selection, forecasting, quantification, procurement, warehousing and distribution of new products, working collaboratively with the Global Fund grant PSM specialist and the TB laboratory TWG. NTBLCP PSM specialist underlined that, to avoid disruption of the supply chain (gaps, wastage), **procurement planning for the introduction of a new TB tool should ideally start 1 year prior to its implementation**, including considering the phase out of the older tool(s) as appropriate. Key steps of the process are illustrated in figure 8 below.

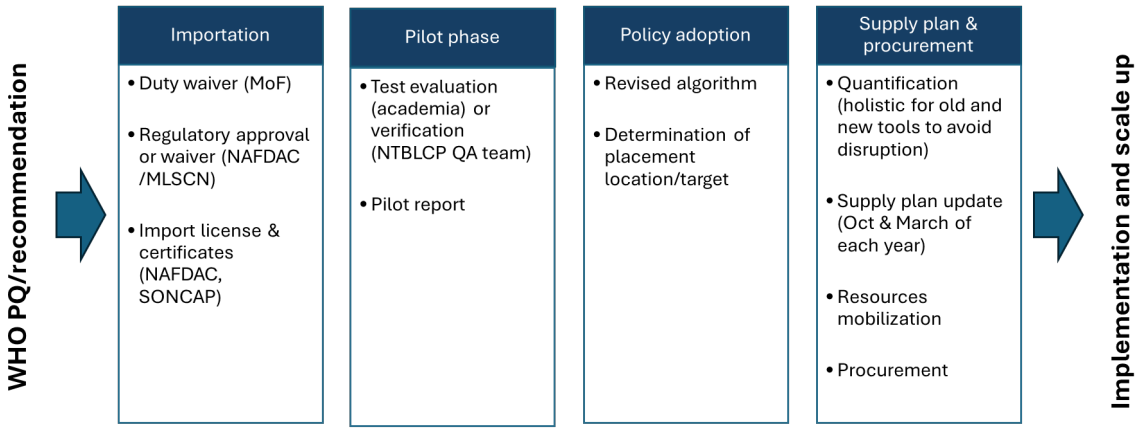

Figure 8: Overview of the supply chain processes for imported TB IVDs and medical devices.

Requirements for imported products:

As specified in the related NAFDAC guidelines[55], importers are subjected to document screening and inspection by NAFDAC Port Inspection Directorate (PID) jointly with other relevant government agencies (ie: SON as per the below details) prior to product release.

In addition, importers of **testing devices/equipment must also comply with safety standards and technical regulations set by SON** for import in Nigeria, whereas medicines & pharmaceuticals are exempted[56]. Specifically, importers must fulfill the requirements of the Offshore Conformity Assessment Program (SONCAP) as stipulated:

- Importers must register with SON
- **Product certificate** (either as unregistered, registered or licensed status) **issued to the exporter** following verification and testing at country of origin and sanctioning that the product meets required standards and regulations prior to shipment[57]. The product certificate is valid for 6 months (for unregistered product) to 1 year (for registered or licensed products).

[55] Guidelines for Clearing of Imported & Medical Devices at Ports Of Entry in Nigeria. NAFDAC. June 2022.
[56] Essential Features. SONCAP website. Accessed 23rd Dec 2025
[57] Conformity assessments are performed by Independent Accredited Firms (IAFs) on behalf of SON and may include, inter alia, physical inspection prior to shipment, sampling, testing, and analysis in ISO17025 accredited laboratories, audit of production processes and systems, documentary check etc. IAFs are numbering 8 which are : Africa Standards and Certifications, Alberk QA Technic., Bureau Veritas., China Certification and Inspection Group., China Hanson Inspection and Certification Co, LTD., China Standards Inspection Co, LTD., COTECNA Verification Services, Nigeria LTD., Intersip Quality Solutions LTD. Details from SONCAP FAQ. Accessed Dec 15th 2025.

	• **SONCAP certificate issued to the importer** and mandatory for custom clearance. The certificate is valid for one year but can only be used for a single consignment. The SONCAP certificate costs USD 350. • Inspection of the product upon arrival in Nigeria and product registration. **Requirements for locally manufactured products:** Local manufacturers undergo GMP inspection at the time of registration. Local manufacturers of testing devices/equipment must apply to the Mandatory Conformity Assessment Program (MANCAP) for locally manufactured products, to ensure compliance with Government policies on standardization and conformity assessment. **Expected procurement volumes at market entry:** For the year 2026, NTBLCP intends to procure 370 MiniDock MTB instruments as part of the Global Fund NPOC access Fund program, with an anticipated testing volume of 1000 tests per site per year. These numbers are based on the following assumptions, timelines and total number of instruments allocated to Nigeria under the program (370): • Roll-out to high volume facilities in April 2026 • Expansion to low-volume (40) and decentralized (230) testing sites. Following this initial roll out, the government plans to purchase 3,000,000 additional tests through the GDF.
Enablers	▪ Availability of a **National Essential Diagnostics List (NEDL)** which specifies provision for placement of molecular WRDs TB testing at each tier of the laboratory network, from the lower PHC level to national reference laboratory. ▪ MiniDock MTB Test, received **ERPD Listing** in July 2025[58] making it eligible for procurement with Global Fund grant[59] financial support under the NPOC market access program.
Anticipated barriers	The following have been identified through desk review[11,60] and by participants to the country workshop: • Heavy reliance on external funding and limited domestic budget allocation (see details under section of this report) • **Long lead times** from ordering to receipt of products requiring robust advanced planning • **Delays in domestic budget release** at federal, state and LGA levels, **in donor disbursements & operational cash flow problems** leading to procurement delays and **periodic stock-outs** of reagents. • **Fluctuations in local currency/inflation that negatively impacting the supply chain** (both procurement & distribution). • Importers of medical Devices and IVDs must provide **documented satisfactory laboratory analysis report**, else the consignment will be placed on hold.
Timelines	According to the NTBLCP PSM team the following timelines applies: ▪ Procurement planning **1 year prior to planned introduction** ○ Supply plan review meeting twice a year in either October or March

[58] Press release: Pluslife MiniDock MTB Test Receives ERPD Listing. PlusLife 14July 2025. Accessed 6 Jan 2025
[59] List of TB Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy. Global Fund, 15 Dec 2025. Accessed 6 Jan 2025
[60] End-Term Review of Nigeria NSP for TB Control 2015-2020 (Narrative Report). NTBLCP, 2021

	▪ Issuance of NAFDAC/MLSCN regulatory approval: see corresponding sections of this report ▪ Issuance of duty waiver: 2-4 weeks from Ministry of Finance which communicates it to the Customs Department ▪ Issuance of a product certificate: **96 hours** if documentation is complete including product testing results by an ISO 17025 laboratory. ▪ Issuance of SONCAP certificate: **96 hours** ▪ Joint Port Inspection: **1 day** ▪ Lag time between order & delivery via GDF: **3-5 months** ▪ Lag time between order & delivery via Wambo: **8 months**

Early adoption and roll out: health systems & implementation needs

Overview of key steps, tasks and parties involved

Early adoption and rollout steps were mapped based on the recent experience for the Truenat assay introduction and discussed by country stakeholders in the October 2025 country workshop. The following are timelines generated by the breakout group on implementation:

Activity	Timelines	Relevant stakeholders
Stakeholder consultation	**1 week**	WHO, TB Partners, test vendor/manufacturer, FMOH-MLSD, NTBLCP, State TB programmes, MLSCN, IOM, CDC, DOD
Development of the assay-specific implementation roadmap	**3 Days**	WHO, TB Partners, test vendor/manufacturer, FMOH-MLSD, NTBLCP, State TB programmes, MLSCN, IOM, CDC, DOD
National verification of New TB Diagnostics & Review of evidence	**3 Months**	TB Reference Labs, NTBLCP, NEQAL, STBLCP-Lab
Inclusion in the national guideline	**3 Days**	WHO, TB Partners, the vendor, FMOH-MLSD, NTBLCP, State TB programmes, MLSCN, IOM, CDC, DOD
Development of assay-specific guideline, SOP, training materials, and M&E reporting tools	**2 Weeks**	WHO, TB Partners, test vendor/manufacturer, FMOH-MLSD, NTBLCP, State TB programmes, MLSCN, IOM, CDC, DOD
Training of Trainers	**1 week**	NTBLCP, Vendor, STBLCP, TB Ref Labs, TB Partners
Cascade training(s): facility-based, with sensitisation	**3 Days**	NTBLCP, Vendor & STBLCP
Continuous monitoring & supervision	**Quarterly**	NTBLCP & STBLCP
Assay optimization and integration	**TBD**	FMOH, Vendors, etc
Diagnostic Network optimization	**Every 5 yrs**	FMOH, Vendors, etc

Training

According to a 2023 journal article[61] on engaging private laboratories in Nigeria, the type of training that would be required are: Hands-on practical training on use and maintenance of new diagnostic platforms, sample collection and biosafety (including PPE), standard operating procedures and national recording/reporting tools, use of connectivity software (e.g., GxAlert or equivalents), quality assurance and external quality assessment procedures, and supportive supervision/mentorship to ensure standardized practice and retention of skills.

Based on papers by Nwokoye et al.,[62] and Akinboye, Olaoye, and Adeniran,[63] the following cadres should receive training:

- Laboratory technologists
- Supervisors at peripheral facilities
- NTBLCP staff

[61] Taofeekat Ali et al., Partnering with the private laboratories to strengthen TB diagnostics in Nigeria. *J Clin Tuberc Other Mycobact Dis*. 2023
[62] Nwokoye, N et al. Exploring the perspectives of healthcare workers and Program managers on the use of Truenat as a new tool for TB and DR-TB diagnosis in Nigeria: A qualitative study. PloS one. 2024.
[63] Akinbiye D.O. Effect of training on frontline health workers' knowledge and attitude towards tuberculosis screening and case finding in Oyo state, Nigeria. International Journal of Community Medicine and Public Health.

	▪ Frontline health workers at primary health centres, including Community Health Officers (CHOs), Community Health Extension Workers (CHEWs), Registered Nurses/Midwives, and DOTS officers involved in TB screening and laboratories. **EQA** The national EQA program and related processes are described under this report section on *Validation, review of evidence and inclusion into policy by national TB program, including use cases* page 20. Proposed indicators to monitor the implementation of near POC are presented in Annex VI. **Maintenance** The NSP contains an objective to ***'ensure availability of maintenance and service contracts for all equipment at all levels'***.[11] *(p. 160).* The Bureau for Public Procurement mandates that manufacturers and suppliers of health and medical equipment have a service center or service agent in Nigeria with demonstrable competency for servicing/repair of equipment and training of users in operation and management.[64] (p. 7) **Lab information management systems** eTB manager is the national TB case notification system whereas the laboratory network mostly relies on GxAlert as a connectivity solution. Paper based and electronic data management systems co exist, and data entry is mostly done offline at lower tiers of the laboratory network.
Enablers	Country workshop participants identified the following key facilitators for effective implementation of routine testing at the subnational level: ▪ Committed governance and leadership ▪ Comprehensive national regulatory framework ▪ Established national strategic plans, including annual operational plans.
Anticipated barriers	• Participants to the country workshop outlined cross cutting systemic challenges that may affect the implementation of diagnostic tools across all diseases/sectors. These echoed findings from various assessments and reports, (e.g.: the End Term Review of 2015-2020 TB NSP, the Nigeria Digital TB Surveillance System Assessment Report [65]), which were also comprehensively captured in Nigeria NEDL situational analysis (Annex V). • A common finding was the limited in-country financial capacity for sustaining/expanding improvements in lab systems at the closure of externally funded pilot projects. • The Resilient and Sustainable Systems for Health (RSSH) Gaps and Priorities Annex included in Nigeria funding request for Global Fund Grant cycle 7 [66], further illustrates funding barriers to implementation of priority program interventions for lab systems (i.e.: reported gap of USD 10 million for specimen referral and transport system and USD 5.9 million for integration on molecular testing platforms)
Timelines	Typically, based on recent experience introducing molecular testing platforms (e.g. Challenge TB Project for GeneXpert, Stop TB iNTP for Truenat) implementation consists in a stepwise approach involving partners supported pilots followed by NTBLCP led scale up, which may span **several months to years**. (NKCV Nigeria annual report 2023, NTBLCP annual report 2023)[67]. Based on the above table, early adoption and rollout would begin with a stakeholder consultation. Steps from stakeholder consultation through to facility-based cascade training, based on the above estimates would take approximately 25 working weeks, i.e. about **6 months of working time**. Based on the historical example of Truenat (figure 13), national guidelines were updated to include Truenat in June 2021, and by November 2021 an initial 39 Truenat instruments were rolled out. By December 2024, 333 additional Truenat instruments were deployed. Based on this example, the timeline from inclusion in national guidelines to initial (limited) rollout is **5 months**.

[64] Approved Policy for Procurement of Health and Medical Equipment for Tertiary Hospitals. Bureau for Public Procurement, Nigeria,2022.
[65] Nigeria Digital TB Surveillance System Assessment. Stop TB Partnership. Document is not dated, but estimated 2022 based on data therein
[66] Global Fund RSSH Gaps and Priorities Annex. Global Fund Data explorer. 31July 2022. Accessed 2d Oct 2025.
[67] Experience sharing on Truenat implementation in Nigeria at TB CAPT symposium during ASLM LabCoP meeting, October 2022 (at 1hr 02 timestamp)

Scale up: network improvement/optimization and M&E	
Overview of key steps, tasks and parties involved	In 2023, Diagnostic Network Optimization (DNO) work (data mapping, stakeholder engagement) was completed, which uncover limitations for with data completeness/availability and a costed operational plan to address gaps was elaborated by the NTBLCP, supported by CHAI.[68] In terms of connectivity, Nigeria has a National Electronic TB Information Management System (NETIMS). The current NTBLCP strategy contains a key Strategic Objective focused on *Optimising NETIMS (etb-manager, Gx alert/GxAspect, DHIS TB module, and MATS).*[11] (p. 266) In December 2023, an assessment was conducted on the NETIMS system, the enablers and barriers of which are listed below, and which may be relevant for novel TB diagnostics. The 2020 end term review of the last strategic period stated an objective to deploy a national Lab Information Management System (LIMS) that captures all TB diagnostic outputs (POC and reference) with automated instrument connectivity (e.g., GXAlert/other middleware) and ensure interoperability with the national DHIS2 (or DHIS2 TB module) and e-TB Manager via standards-based APIs.[69]
Enablers	▪ Good coordination of TB programs across national and subnational levels and availability of policies and guidelines that support decentralized TB testing, are opened to innovation and that leverage wider health sector strategies to strengthen integration with other disease programs such as HIV, RMNCH. ▪ Experience with conducting DNOs
Anticipated barriers	• The SWOT analysis included Nigeria TB NSP[11], highlights the limited access to TB services in the country that is compounded by the poor integration of TB services with other relevant sectors and the absence of multi-sectoral synergy (page 60). • Sub-optimal data integration due to: o incomplete scale-up of the TB Laboratory Information System and reliance on third-party developers. o hardware and infrastructure constraints (power, internet, server capacity, devices), and inconsistent real-time data availability o Shortage of key human resources for eTB Manager implementation.[70] o Insufficient national coverage of electronic data systems at the facility level[71] • Current major barriers include sudden withdrawal/cancellation of donor funding and other financing constraints described in the section of this report on *Considerations on the current TB funding landscape* resulting in shortages of laboratory commodities and operational staff.
Timelines	Based on historical timelines for Truenat (figure 13), initial rollout of Truenat tools was initiated in November 2021, and in December 2024, the number of Truenat machines were increased to 33 units. Hence, initial rollout to scale up may take approximately **three years**. Connectivity may take longer as conversations were still ongoing at the time of the country workshop,

[68] Annual TB Report NTBLCP, 2023.
[69] Federal Ministry of Health, Nigeria, *End-Term Review of Nigeria's National Strategic Plan for Tuberculosis Control 2015- 2020*.
[70] Olusegun A H, 'The Digital Transformation of TB Surveillance Systems: Practical Lessons and Country Perspectives', USAID DIAH, 2023.
[71] Hassan, 'The Digital Transformation of TB Surveillance Systems: Practical Lessons and Country Perspectives'.

Considerations on the current TB funding landscape

The overall budget needed to implement the NigeriaTB NSP 2021-2026[72] is estimated at USD 2,356,750,000, of which ~23% is to be allocated to case detection and diagnosis. Among the strategic directions of the TB NSP 2021-2026, the NTBLCP aimed to increase the share of domestic funding from 8% at baseline to 50 % by 2026. However, as of 2025, the share of domestic funding for financing TB control activities had been reduced to 5.2 % with an overall **a gap of 73%,** as illustrated below. According to WHO[73], sources of funding available for TB control activities in Nigeria in 2024 were broken down as follows: 18% domestic funds (USD 20 million), 22% from USAID (USD 25 million) and 60% Global Fund (USD 69 million). This reliance on external aid made the country particularly vulnerable to disruptions following reductions in development assistance in early 2025.

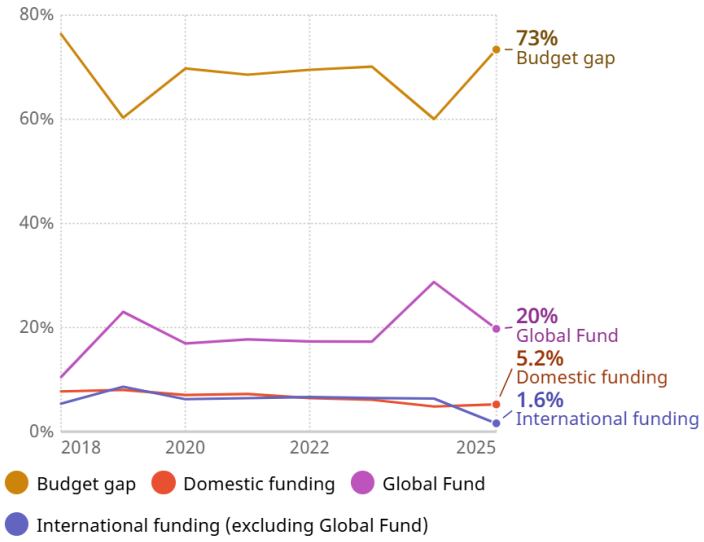

Figure 9: Source of funding and funding gap reported for the TB-specific budget (%) *(adapted from the WHO TB data hub)*

Nigeria is the Global Fund largest portfolio investment, with USD 993 million granted for the 2024-2026 period (grant cycle 7)[74], of which USD 146,083,214 were allocated to the TB component. This included support for the purchase of consumables for 5 + million molecular tests (Xpert and Truenat cartridges, TB LAMP reagents), sample transport logistics, and expansion of connectivity capacity (GX Alert) as well as implementation of PPM activities in 22 states and active TB case finding among key and vulnerable populations (e.g. children, inmates, nomadic and displaced populations)[75].

Nigeria also ranked among the top 10 recipients for USAID funding with about USD 2.8 billion granted to the health sector between 2022 and 2024. Following the USAID closure, the country faced an absolute cut of USD 178 million overall [76].

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[72] National Strategic Plan for Tuberculosis Control 2021-2026, page 152. Nigeria FMoH. 2021
[73] Global TB report 2025. WHO, 2025. Section 4.1 Financing for TB prevention, diagnostic and treatment services.
[74] Update : Nigeria and Global Fund Launch New Grants to Reinforce Progress against HIV, TB and Malaria. The Global Fund, February 2024. Accessed 15 December 2025.
[75] Nigeria TB/HIV funding request (allocation Period 2023-2025). The Global Fund Data explorer. Accessed 15 December 2025.
[76] Demystifying Africa's dependence on foreign aid. Mo Ibrahim Foundation, Aug 2025. Accessed 15 Dec 2025.

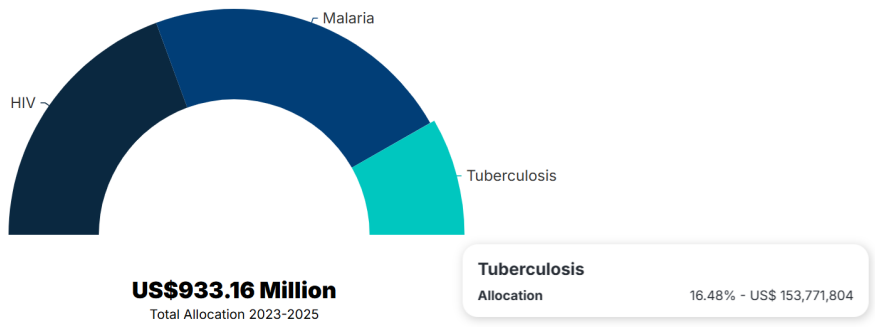

Figure 10: Global Fund allocation to Nigeria for grant cycle 7 *(Source: Global Fund Data explorer)*

A Stop TB Partnership report[77] highlighting early impact of funding cuts on response efforts in high TB burden countries indicated that in Nigeria specifically, 1 national USAID-funded advisor for laboratory services and 1800 staff across 18 high burden states had been terminated, whereas procurement of 200 000 GeneXpert tests has been halted, affecting screening, PPM and outreach activities.

Nigeria government leadership quickly mobilized mitigate the impact of funding cuts with some notable highlights below:

- By 2025, Nigeria had increased health spending from ₦434B (approximately US$304M) (2018) to ₦2.4T (approximately US$1.7B) (2024), i.e. 5.18% of the federal budget with the intention of enrolling 4 million citizens in health insurance by 2030.[78]
- The government established a multisectoral committee (including the MoH and MoF) charged to develop a transition and sustainability plan to ensure the continuity of essential health services[79].
- Under the advocacy of the Global TB Caucus member Amobi Godwin Ogah, Nigeria's legislature allocated USD 457 million for health programs to address external aid shortfalls[80].
- On World TB Day, Nigeria First Lady pledged ₦1B to fight against TB [81]
- During the board meeting of the Stop TB partnership, Muhammed Ali Pate, announced the country's intention to allocate USD 54 million from its domestic resources to purchase TB drugs and diagnostics through the Global Drug Facility[82].

Despite the aforementioned challenges, the NTBLCP indicated during the 2025 TB Union Conference that **the country had still notified more cases in 2025 compared to the year prior**, an achievement which was made possible by 1) reallocating available resources (human and financial) based on a maximum yield index, 2) batching samples and reducing transportation schedules and 3) leveraging virtual trainings.

On December 19th, the Nigerian government signed a new **bilateral technical health system MoU** with the United States (US) government for the 2026-2025 period, with financial commitments totaling USD 2 billion for the US and USD 3 billion domestic funding[83]. This MoU, incorporates, inter-alia, support to improve laboratory systems, including **100% of lab commodities covered by the US in 2026**, with Nigeria progressively taking over in the next 5 years.

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[77] Report on the Impact of US Government Funding Halt on TB Responses in High TB Burden Countries. Stop TB Partnership, March 2025. Accessed 31st July 2025
[78] Vivek Panwar, "Nigeria restates commitment to sustainable health financing, universal coverage" P4H Social Protection Health Network, 3 September 2025. Accessed 8 January 2026
[79] Nigeria announces measures to soften impact of USAID programs' suspension. European AIDS treatment Group.4th Feb 2025. Accessed 12th Jan 2026.
[80] Africa's Tuberculosis Funding Crisis: Moving Beyond External Saviors. Think Global Health 30th July 2025. Accessed 12th Jan 2026.
[81] Social Media Post. Nigeria Federal Ministry of Information and National Orientation. 25th March 2025. Accessed 12th Jan 2026.
[82] How the Stop TB board plans to future-proof tuberculosis finance. Devex, 12th Nov 2025. Accessed 12th Jan 2026.
[83] Nigeria & United States Sign Landmark Agreement to Strengthen Health Security, Expand Primary Care, And Drive Self-Reliance. 19th Dec 2025 FMoH.

Critical Path Analysis country roadmap(s)

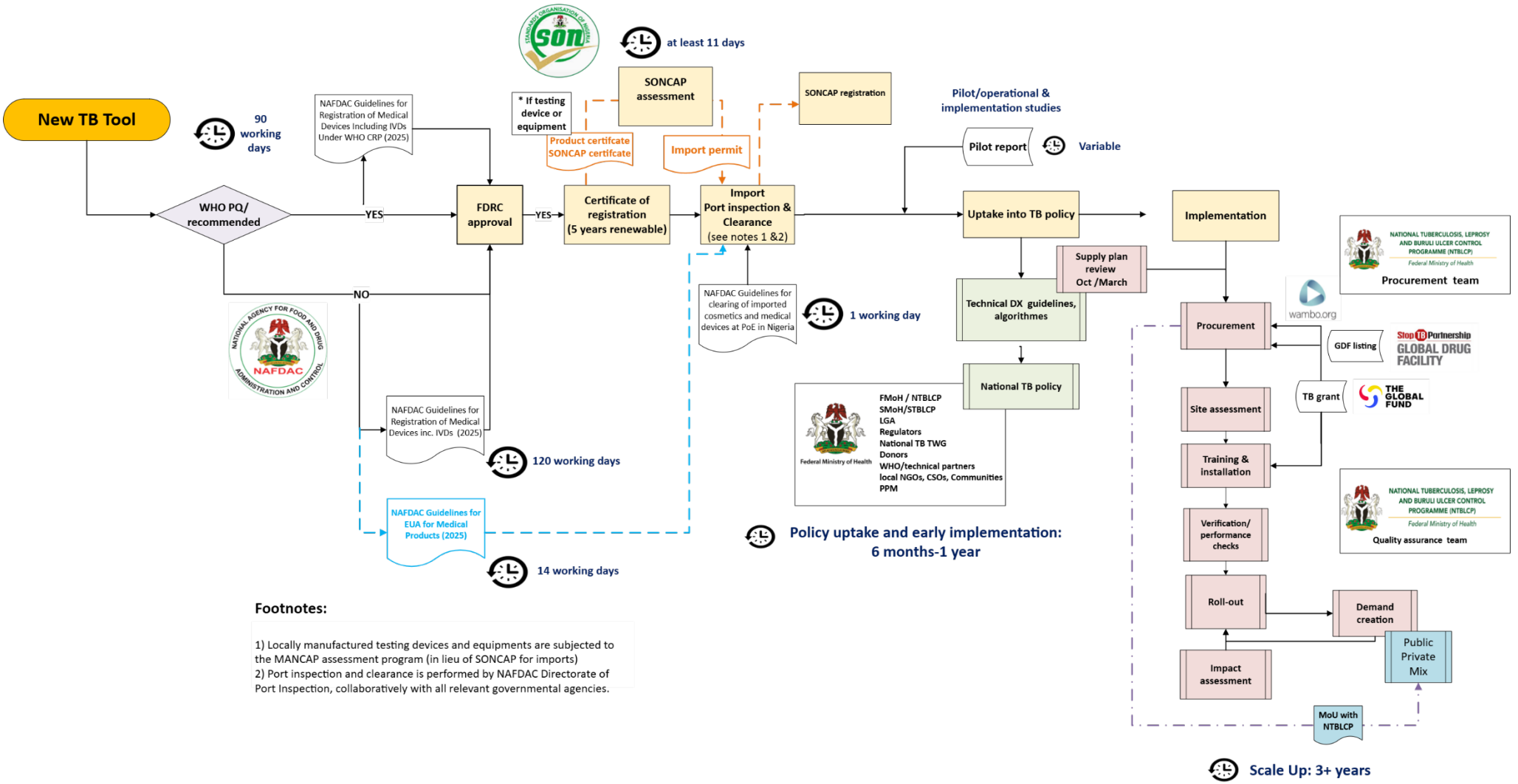


Figure 11: Roadmap for introduction of new TB diagnostics in the public and private sectors (NAFDAC entry)

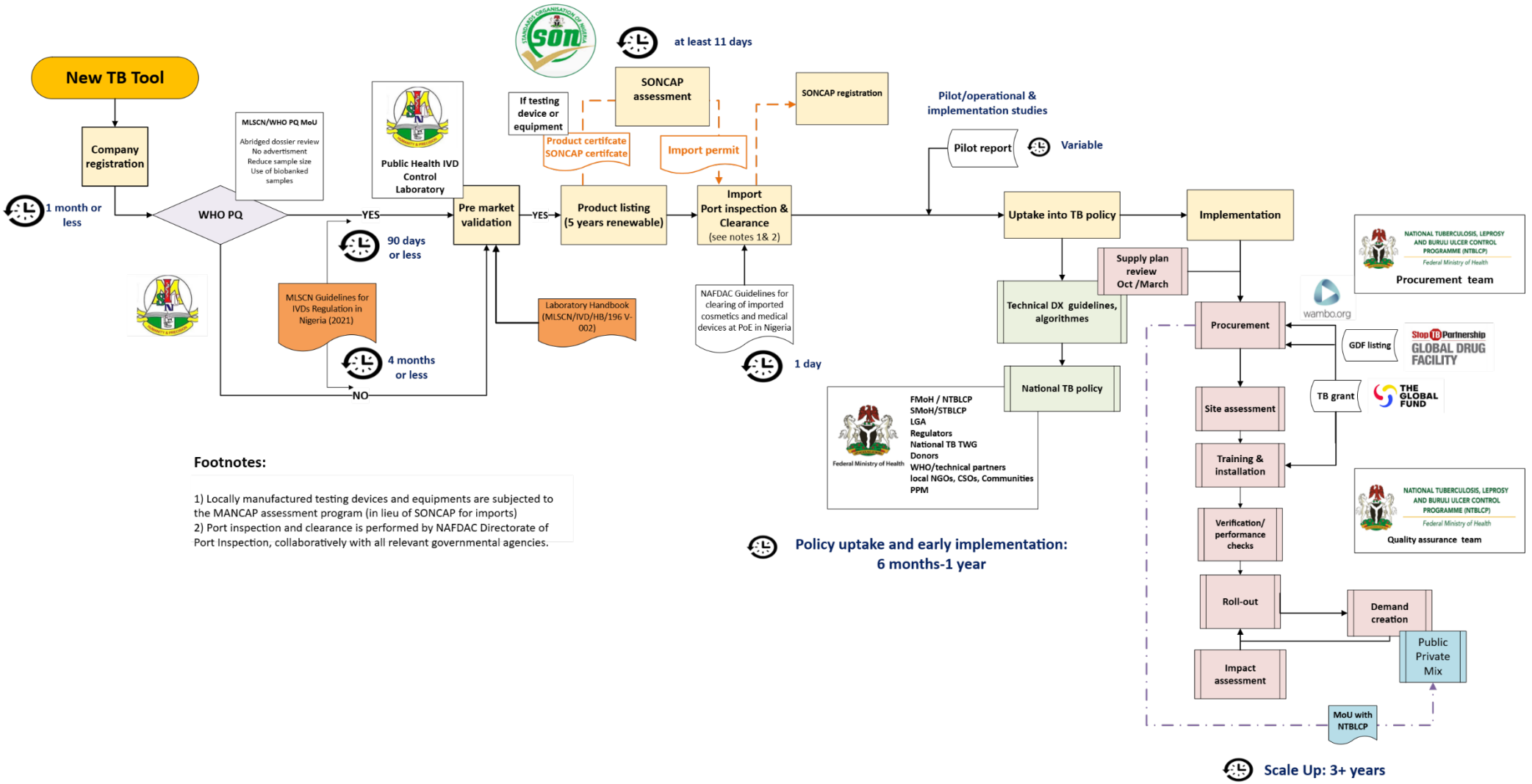


Figure 12: Roadmap for introduction of new TB diagnostics in the public and private sectors (MLSCN entry)

Historical data and timelines

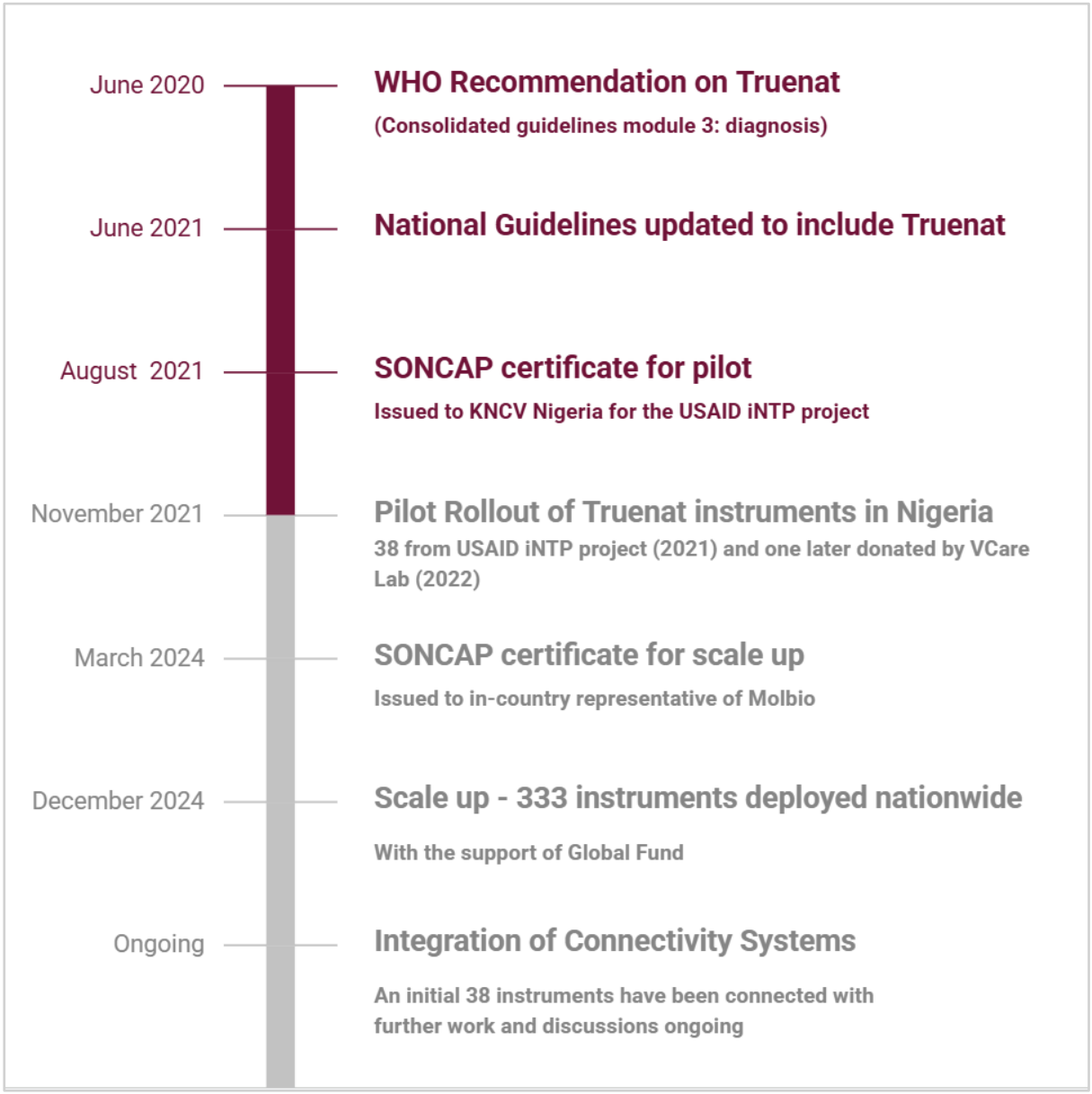


Figure 13: Historical timelines for the introduction of the Truenat assay in Nigeria

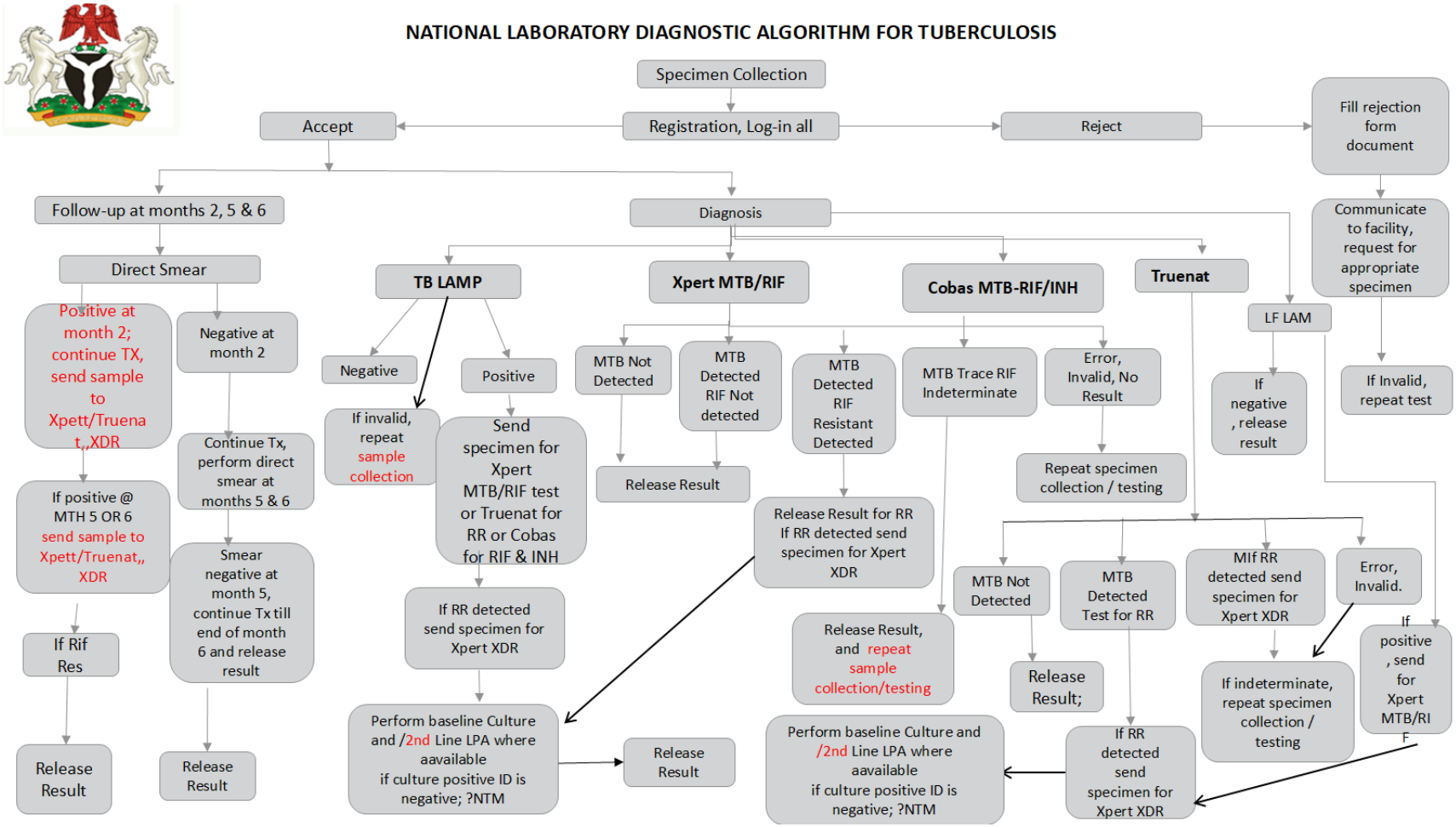
Recommendations and conclusions

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

Recommendations for the National Regulators (NAFDAC and MLSCN)	▪ To elucidate/connect potentially duplicative processes **to reduce confusion, administrative and financial burden for manufacturers**. ▪ To ensure that the listing of registered medical devices and IVDs be publicly available (i.e.: online) ▪ To advocate for ratification of the African Medicines Agency treaty ▪ NAFDAC to pursue efforts aiming at strengthening national regulation for medical devices and IVDs (WHO GBT) ▪ To align with AU/AMA regional initiatives/decisions to accelerate diagnostic products (incl. TB) introduction.
Recommendations for FMoH/SMoH/NTBLCP /TB NRL	▪ To develop a **priority plan to transition lab system strengthening from external to domestic funding, including clear KPIs, targets, and timelines**. ▪ To include TB diagnostics services in NHIS/BHCP to increase access and reduce out of pocket expenditures. ▪ To ensure timely implementation of the pilot roll out of the MiniDock MTB. ▪ To mobilize (domestic) funding to support community health extension workers. ▪ To develop a communication plan outlining steps to be taken in educating/ promoting awareness about various stakeholders. ▪ To promote meaningful engagement and an inclusive process to design people-centred interventions for nomadic and displaced populations, including designing context sensitive messaging taking into consideration local languages, beliefs, myths and misconceptions.
Recommendations for in-country technical partners (ie. IHVN) and indigenous civil society organizations	▪ To maintain support for operational and implementation studies informing optimal introduction of new TB diagnostic tools. ▪ To support the NTBLCP for **the implementation of community led monitoring** for strengthening advocacy and feedback to improve programming and diagnostic service delivery
Recommendations for test developers	▪ To consult guidelines (NFADAC, MLSCN, SON websites and application portals) and **ensure dossier completeness** when applying for registration. ▪ To consider leveraging in country technical expertise for performance evaluation of new tests upstream of registration. ▪ To ensure that devices and IVDs introduced through waivers proceed to full registration with all relevant regulatory authorities, as per national guidelines.
Recommendations for WHO and PQ teams	▪ To accelerate as feasible the review of evidence and publication of policy statements and recommendations for novel TB diagnostics. ▪ To continue the engagement and collaboration with Africa CDC and AMA to ensure synergies and complementarity between continental and WHO regulatory approvals processes.
Recommendations for Donors (Global Fund, Unitaid, etc)	▪ Ensure that market shaping initiatives, such as the Global Fund market access program for the MiniDock MTB, incorporate cost-effectiveness analysis to better inform decision making and selection of tools at country level. ▪ To consider and support the dissemination of findings from the present critical pathway analysis to inform the market entry of upcoming new TB diagnostic tools.

Annexes

Annex I: TB diagnostic algorithm[84].



[84] *Nigeria near POC implementation plan*. NTBLCP, Global Fund Stakeholder Workshop for early adopters of Near Point-of-Care TB Diagnostics, Nairobi, Kenya, 20-21st October 2025.

Annex II: Nigeria representation in continental regulatory committees.

AMRH regional centers of excellence	Representative
Quality Assurance and Quality Control of Medicines	NAFDAC
Training on Core Regulatory Functions	University of Ibadan

Annex III: List of participants to the in-country consultation and validation workshop (27th-28th December 2025)

No.	Name	Position and Affiliation
1.	Adesigbin Clement	Ag. Coordinator, NTBLCP
2.	Agha Janet	Director, Laboratory, NTBLCP
3.	Ejilude Oluwaseun	GF/TB Coordinator, IHVN
4.	Paulinus Offutalu	Laboratory Manager, MLSCN-IVD
5.	Kayode Martins	KFY Account Manager, Abbott
6.	Sani Khalil. A	KFY Accountant, Abbott
7.	Ahmed Badawi	SMoH Kano State STBLCP
8.	Nasifat Isa Salisu	PCHT, FCT PH
9.	Sunny John Kwaghe	Janna Health Foundation, Program Officer
10.	Muhammad S Umar	SQAO
11.	Suleman Mikailu	MLS/HW BSL2/BSL3, NTBLCP Zaria
12.	Olayide Akanni	National coordinator, Civil Society for the Eradication of TB
13.	Bassey Emmana Ekpenyong	Lab manager, Zankli Research centre Bingham University
14.	Elowu Emua	Director, FMOH-MLSD
15	Adegoke Eunice	Director, NAFDAC
16	Ezekiel Ifunanya	Deputy Director, NAFDAC
17	Busari Olusegun	Regional Director, Cepheid
18	Armachie Joseph	Technical Officer, Africa CDC
19	Jubril Kareem	Technical officer Lab systems strengthening, WHO country office
20	Olabamiji Jamiu	Director, Mcpage Investment
21	Adaran Tolulope	Specialist, NTBLCP
22	Njedeka Maduka	Manager, Molbio Diag LH
23	Deborah Bulus	Laboratory Specialist, NASCAP
24	Omolara Emmanuel	Deputy Director, Lab, NASCAP
25	Ajani Love Adeiye	LPO, FMOH-MLSD
26	Prisca Ajiboye	Director, KNCV TB Plus
27	Faloni Gbenga	Lab Specialist NTBLCP
28	Victor Ombeka	Senior Technical Advisor, NTBLCP

No.	Name	Position and Affiliation
29	Emperor Ubiochioma	PMU R, NTBLCP
30	Rita Akpakpan	MLS, NTBLCP

Annex IV: Operational studies on new TB diagnostic tools in Nigeria

In collaboration with the NTBLCP, local research centres undertake a wide range of studies that primarily qualify as Operational Research (OR) — systematically designed to improve the efficiency, effectiveness, and quality of tuberculosis (TB) and HIV diagnostic and treatment services in real-world settings. These studies aim to identify what works, where, and how best to implement it within Nigeria's health system. The aim is to aim is to strengthen diagnostic systems by producing local evidence to guide national health policies.

A representative, but non exhaustive, list of ongoing and previous operational research on TB diagnostic tools of interest for this CPA has been developed by representatives of research centres (notably Zankli Research Center: Bassey Emmana Ekpenyong and Jana Health Foundation Sunny John Kwaghe) as part of the working group on production of local evidence for adoption of new TB diagnostic tools during the country validation workshop.

- **SMART4TB–ADAPT Study (2023- till date):** Assessed and evaluated the use of tongue swabs for novel tools such as **Pluslife**, **Truenat Molbio MTB Ultima Chips**, **Truelyse**, and **GeneXpert**, all in comparison with sputum on GeneXpert and culture, to improve point-of-care TB diagnosis. Study was initially funded by USAID via University of California San Francisco USA and other partners from Johns Hopkins University (USA), KNCV from 2023 up until February 2025 then we received funding from Bill and Melinda Gates Foundation

- **STAR4ALL Project. (2022- till date):** a project led by LSTM, implemented in two phases and targeting key and vulnerable populations, particularly in areas with limited laboratory access where TB diagnostic testing is typically unavailable. The project evaluates and promotes the adoption of innovative TB diagnostic tools (i.e.: **GeneXpert Edge, Fujifilm SILVAMP TB-LAM, Eurolyser CRP, CAD CXR**) and various test combinations in primary healthcare settings. Its goal is to expand access to rapid testing and early TB detection for underserved populations through both primary care facilities and community outreach programs. It is funded by UNITAID.

- **Multi-site Field Trial of the FUJIFILM SILVAMP TB LAM II Including the Diagnostic Accuracy of a Urine Concentration Device (UCD):** a two-stage, prospective **multi-center cross-sectional field trial** evaluating the diagnostic performance, accuracy, feasibility, acceptability, and cost-effectiveness of **FUJIFILM SILVAMP TB LAM II** with and without the **Urine Concentration Device (UCD)** for detecting TB among PLHIV and HIV-negative individuals. The aim was to generate evidence informing upcoming **WHO recommendations** by **May 2025 (FujiLAM II)** and **May 2026 (FujiLAM II + UCD).**

- **A One-Stop Shop for Same-Day Diagnosis and Management of TB and HIV (2018, EDCTP funded):** Evaluated the diagnostic performance of **CRP**, **Truenat Molbio MTB/RIF**, and **Xpert Ultra MTB/RIF**. Notably, **results from this project contributed to Nigeria's national adoption of Truenat Molbio** for the diagnostic tool of TB.

- **Acute Phase Proteins and IP-10 as Triage Tests for the Diagnosis of Tuberculosis (2018, EDCTP funded):** Investigated host biomarkers for early TB screening, contributing to translational operational research.
- **Systematic Review of Pooling Sputum as an Efficient Method for Xpert MTB/RIF TB Testing During the COVID-19 Pandemic (2020, EDCTP Funded):** Evaluated an innovative cost-saving testing approach to optimize cartridge use during supply shortages.

Annex V: Most common barriers for access to diagnostics in Nigeria

Challenges	Number of institutions (n=62)
Non-availability of Multiplex tests designed for different diagnoses of common diseases e.g. malaria, typhoid, pneumonia etc. with similar clinical features	53 (85.5)
Non-availability of digital Laboratory Information Management System (LIMS)	48 (77.4)
Lack of funds for further diagnostic tests	47 (75.8)
Inadequate Remuneration	46 (74.2)
Limited access to internet	46 (74.2)
Inadequate number of qualified personnel	45 (72.6)
Non-availability of Quality Control materials	44 (71.0)
Inadequate power supply	43 (69.4)
Limited access to telecommunication	43 (69.4)
Lack of institutional support for training/retraining	43 (69.4)
High cost of diagnostic test kits	42 (67.7)
Non implementation of LQMS-ISO 15189	40 (64.5)
Patients reluctance to be transferred for additional tests or a specialized consultation	39 (62.9)
Absence of POC diagnostic tests with special software to help imaging interpretation	39 (62.9)
Inefficient Procurement System	38 (61.3)
Frequent Stockouts	37 (59.7)
Lack of funds for transportation & costs of additional diagnostics	37 (59.7)
Limited Access to POC	36 (58.1)
Deficient Lab Services (Unreliable; Poorly equipped)	36 (58.1)
Lack of Knowledge of QMS by staff	35 (56.5)
Lack of potable water supply	26 (41.9)
Inter-professional rivalry	24 (38.7)
High Staff Turnover/Poor Retention	23 (37.1)
Shortage of Specialists at Referral Facilities	18 (29.0)
Unqualified practitioners	17 (27.4)
Low-quality services at referral facilities	15 (24.2)

Barriers	NGO/FBO n=7 (%)	Private n=11 (%)	Public n=44 (%)
Non-availability of Multiplex tests designed for different diagnoses of common diseases e.g. malaria, typhoid, pneumonia etc. with similar clinical features	7 (100)	6 (54.5)	40 (90.1)
Non availability of digital Laboratory Information Management System (LIMS)	5 (71.4)	5 (45.5)	38 (86.4)
Non-availability of Quality Control materials	6 (85.7)	4 (36.4)	34 (72.3)
Inadequate Remuneration	5 (71.4)	4 (36.4)	37 (84.1)
Lack of Knowledge of QMS by staff	5 (71.4)	4 (36.4)	26 (51.1)
Limited access to internet	5 (71.4)	4 (36.4)	37 (84.1)
Absence of POC diagnostic tests with special software to help imaging interpretation	6 (85.5)	4 (36.4)	29 (65.9)
Inadequate number of qualified personnel	4 (57.1)	3 (27.3)	38 (86.4)
High cost of diagnostic test kits	3 (42.9)	7 (63.6)	32 (72.3)
Patients reluctance to be transferred for additional tests or a specialized consultation	4 (57.1)	6 (54.5)	29 (65.9)
Inadequate power supply	4 (57.1)	5 (45.5)	34 (72.3)
Lack of funds for further diagnostic tests	4 (57.1)	5 (45.5)	38 (86.4)
Lack of institutional support for training/retraining	4 (57.1)	4 (36.4)	35 (79.5)
Deficient Lab Services (Unreliable; Poorly equipped)	4 (57.1)	2 (18.2)	30 (68.2)
Limited access to telecommunication	5 (71.4)	2 (18.2)	36 (81.8)
Limited Access to POC	5 (71.4)	1 (9.1)	30 (68.2)
Lack of funds for transportation of samples; costs of additional diagnostics	4 (57.1)	1 (9.1)	32 (72.3)
Non implementation of LQMS-ISO 15189	4 (57.1)	6 (54.5)	30 (68.2)
Lack of potable water supply	3 (42.9)	4 (36.4)	19 (43.2)
Shortage of Specialists at Referral Facilities	3 (42.9)	2 (18.2)	13 (29.5)
Low-quality services at referral facilities	3 (42.9)	2 (2.3)	10 (22.7)
Unqualified practitioners	2 (28.6)	0 (0.0)	15 (34.1)
High Staff Turnover/Poor Retention	2 (28.6)	3 (27.3)	18 (40.1)
Frequent Stock outs	2 (28.6)	2 (18.2)	33 (75)
Inefficient Procurement System	2 (28.6)	1 (9.1)	35 (79.5)
Inter-professional rivalry	0 (0.0)	0 (0.0)	24 (54.5)

Extracted from : *Nigeria National Essential Diagnostics List. FMoH. May 2022* (Table 4 and 5, page 55-56)

Annex VI: M&E indicators for implementation of near POC TB diagnostics in Nigeria

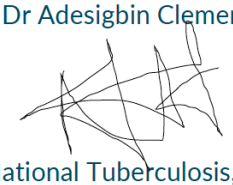
Indicator	Definition / Measurement
# of people tested using NPOC for TB diagnosis	Total TB suspects who received an NPOC test
# of positive NPOC results	Number of suspects with positive TB results
# of negative NPOC results	Number of suspects with negative TB results
# of positive cases initiated on treatment	Treatment initiation following positive test
# of NPOC tests by setting	Disaggregated by site type – microscopy, PHC, HIV clinic, etc.
Type of samples tested	Sputum, tongue swab, or other sample types
Demographics / population categories	Age, sex, key and vulnerable populations
# of TB cases with HIV status documented	Among those diagnosed via NPOC
# of positive NPOC tests with DST result	Confirmed drug resistance testing outcomes

Reference: ***Nigeria near POC implementation plan.*** NTBLCP, Global Fund Stakeholder Workshop for early adopters of Near Point-of-Care TB Diagnostics, Nairobi, Kenya, 20-21st October 2025.

Acceptance of Findings by National TB Program

The National Tuberculosis, Buruli and Leprosy Control Program (NTBLCP) at Nigeria Federal Ministry of Health, hereby acknowledges and accepts the content of the report as complete and satisfactory. By signing this agreement, the NTBLCP confirms that the findings may be relied on for the next steps in introducing novel TB diagnostics in the country.

Dr Adesigbin Clement Olufemi



Acting National Coordinator – National Tuberculosis, Buruli Ulcer and Leprosy Control Program

Federal Ministry of Health Nigeria