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Critical Path Analysis for New TB diagnostics in Africa region

Nigeria

January 2026

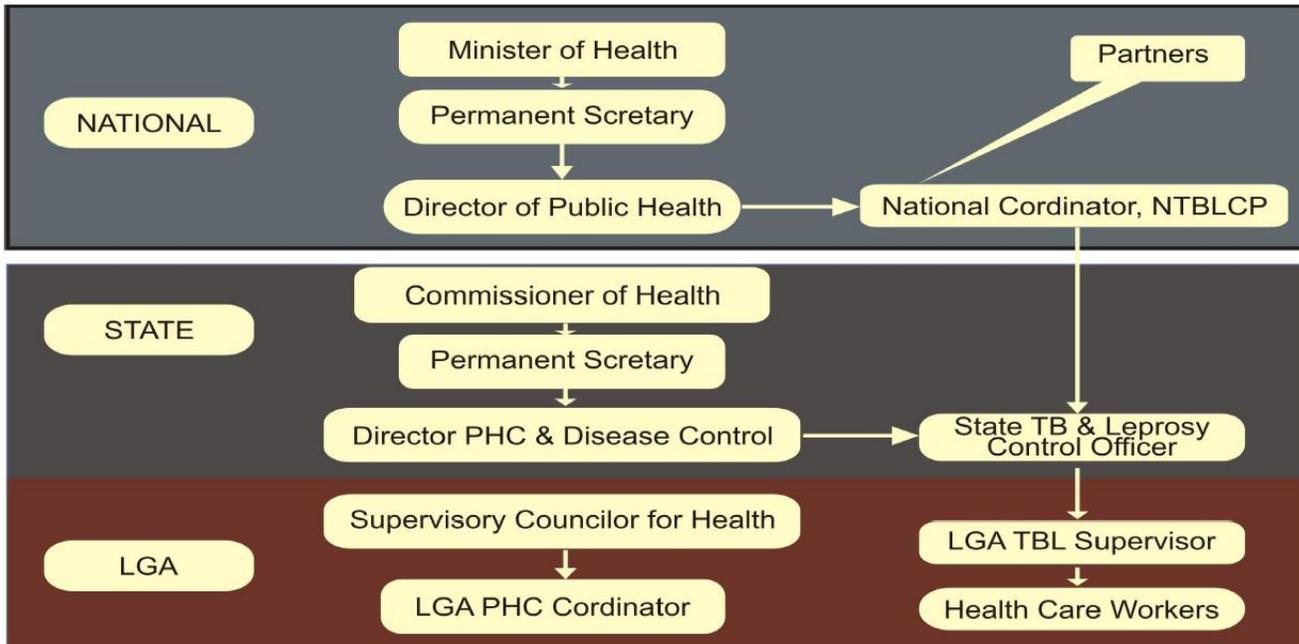


Photo credit: pexels.com



Figure 1: Nigeria country profile (World TB global report 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.)

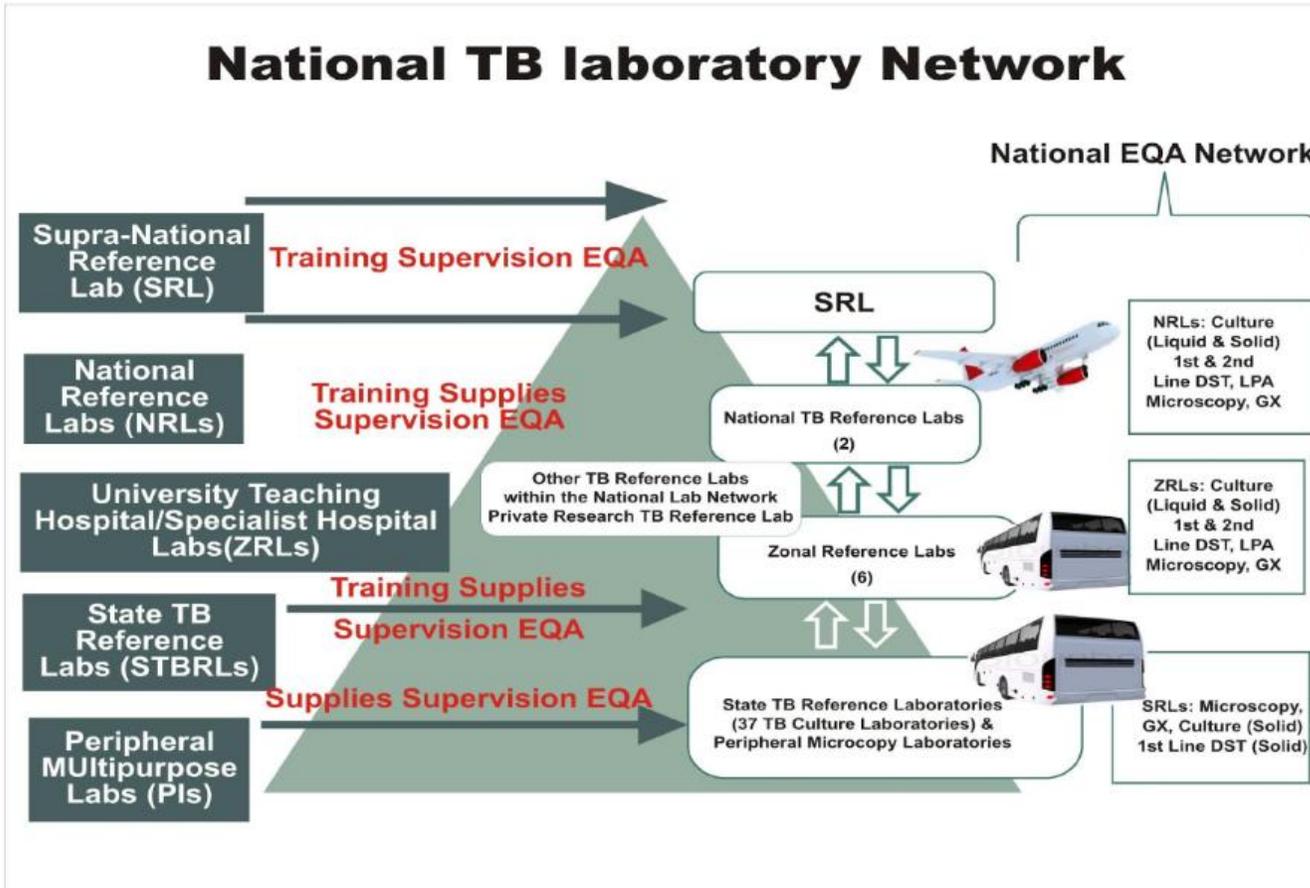


TB, Leprosy and Buruli control activities in Nigeria are coordinated by the National Tuberculosis and Leprosy Control Program (NTBLCP) established in 1989

NTBLCP operates through three levels of governance :

- National (NTBLCP central unit)
- State (State TB and Leprosy Control Program or STBLCP)
- Local government area (Local Government Tuberculosis and Leprosy Supervisor LGTBLS)

Figure 2: Organization & operational levels of Nigeria NTBLCP (TB NSP 2021-2026)



NTBLCP laboratory network is organized in 4 tiered levels :

Level 1 (peripheral): laboratories located within primary health centres, 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 NRLS

- the Nigerian Institute of Medical Research (NIMR), Lagos (Southern region) parastatal
- the National TB and Leprosy Training Centre (NTBLTB), Zaria (Northern Region).
- the NRLs are affiliated with Milan SRL in Italy

Figure 3: Nigeria national TB network (TB NSP 2021-2026)

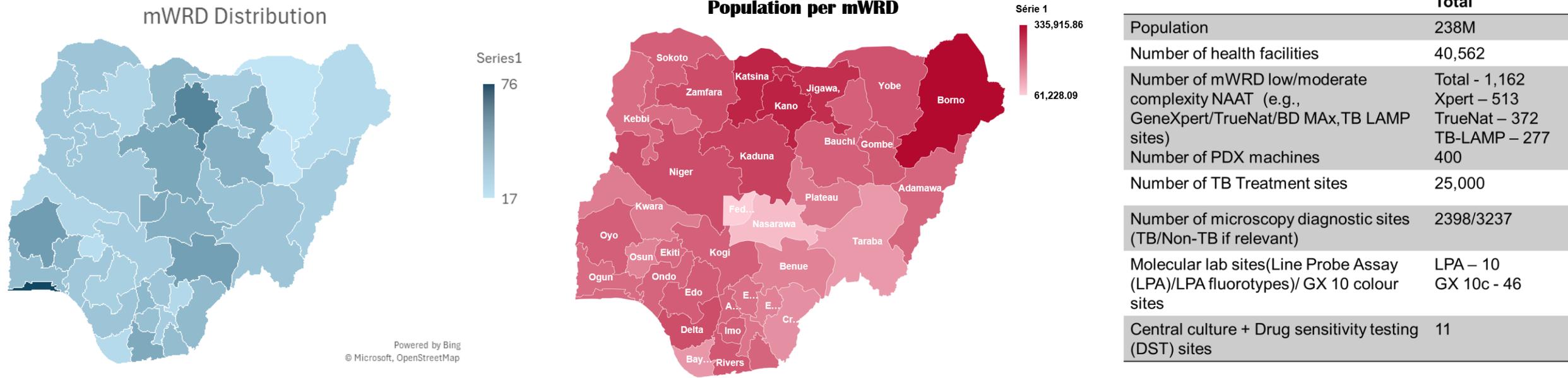
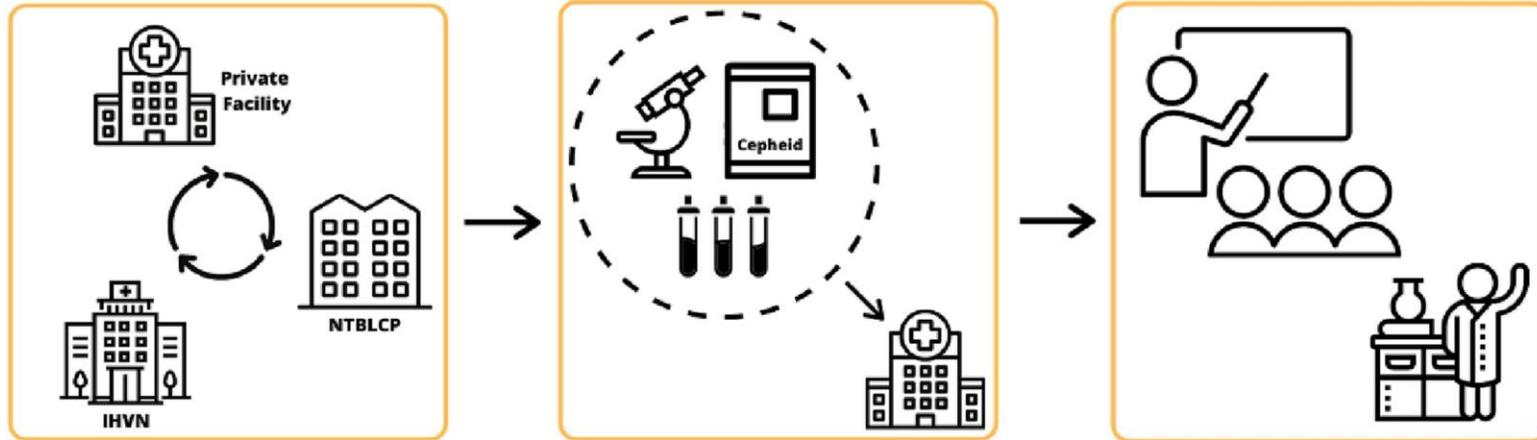


Figure 4: Distribution and coverage of mWRDs in Nigeria (Nigeria NPOC implementation plan Nov 2025)



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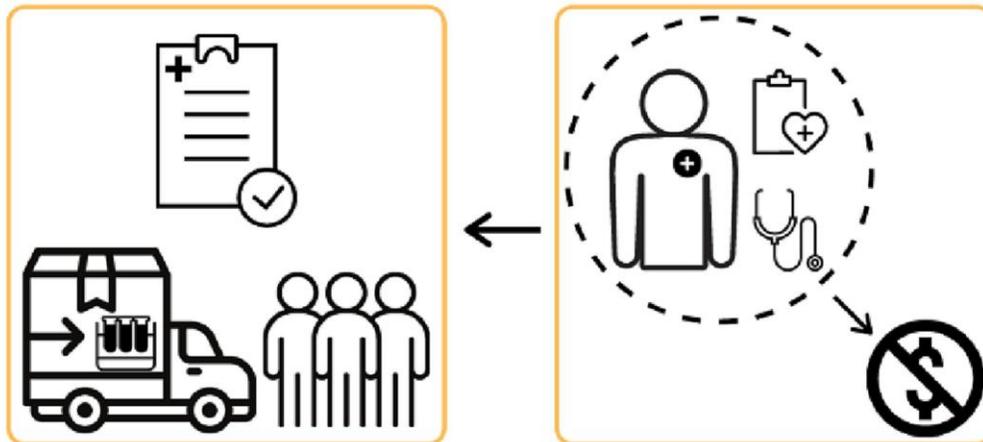
Public Private Mix (PPM) model



Tripartite Memorandum of Understanding is signed between the entities

Private facility is integrated into the national commodity distribution network

Facility staff is trained through hands-on support and supervision

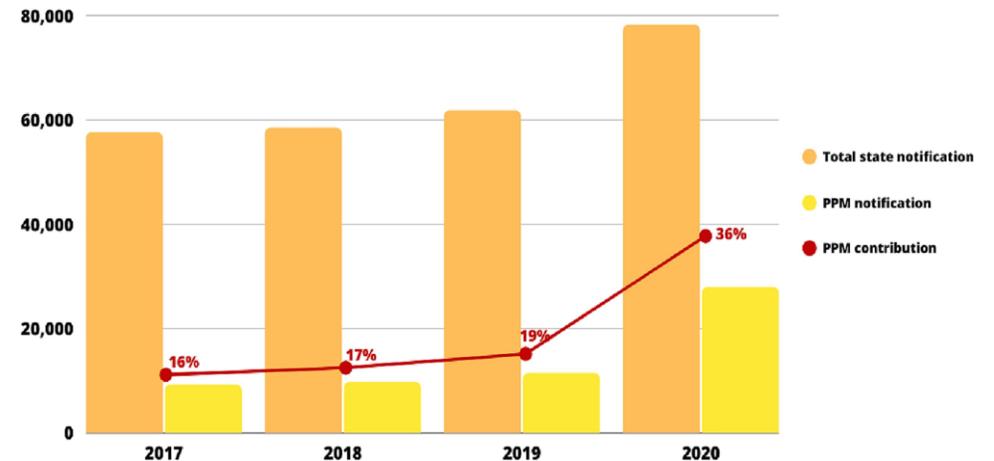


Linkage coordinators coordinate the arrival of samples, return of test results, and complete documentation in the national reporting tools

Private laboratories conduct diagnostic tests and document results in the NTBLCP reporting channel; they cannot charge patients any fee

Figure 5: PPM model in Nigeria

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

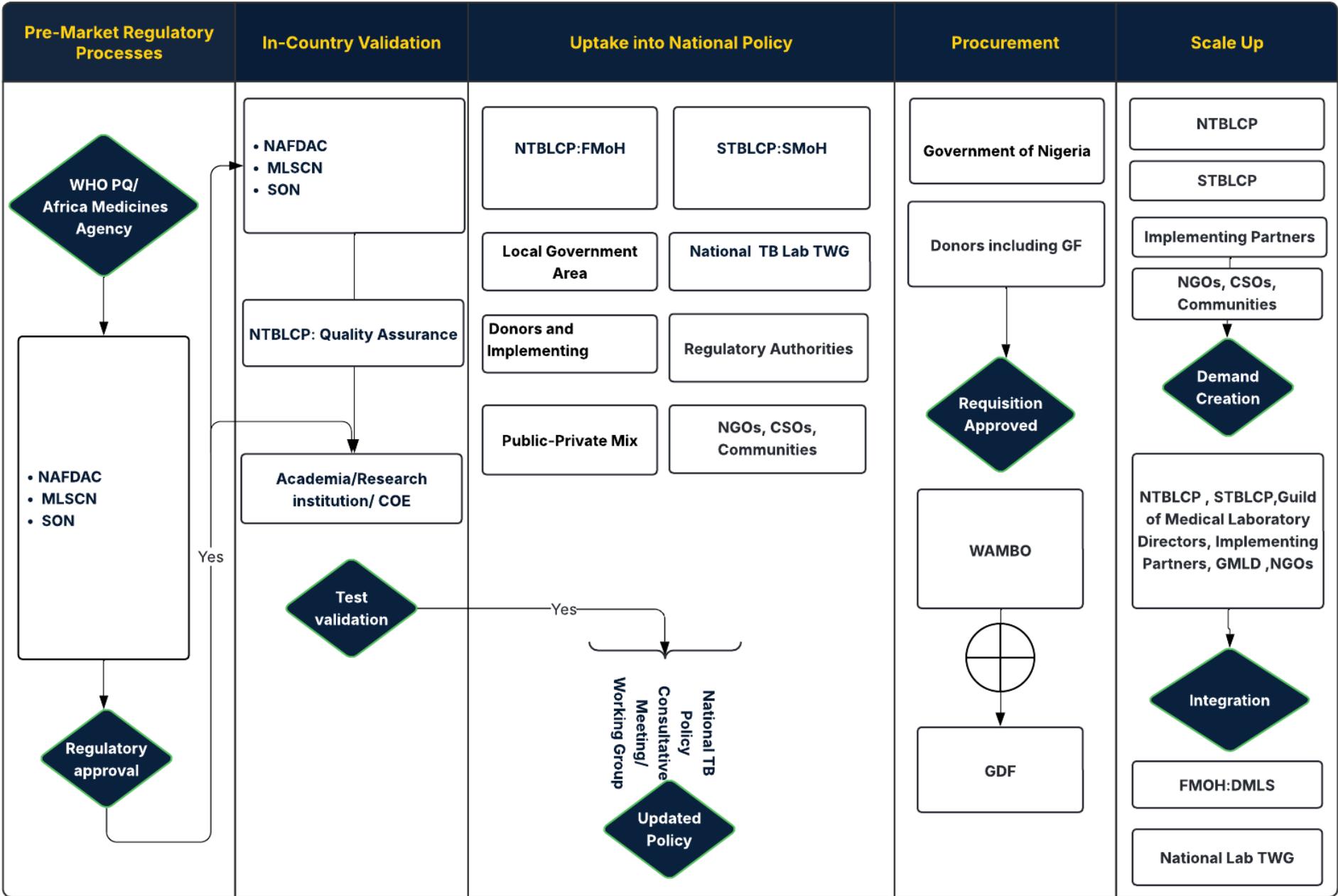




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Key findings

Stakeholders map





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Key findings

Regulatory approval & uptake into
national policy

Regulatory : reliance & harmonization

	National Agency for Food and Drug Administration and Control (NAFDAC)	Medical Laboratory Science Council of Nigeria (MLSCN)
Reliance/ collaborative pathways		
Recognized Regulatory Authorities*	GHTF WLA ML3-4 NRAs EMA WHO PQ	WHO PQ FDA, CE marking
Regional harmonization	Regional economic communities (WA MRH) AMRH	
Continental mechanisms		
African Medical Agency (AMA) ratification	No	No
Party to Africa Medical Device Forum (AMDF) -TCs	yes	yes
Africa CDC Diagnostic advisory committee (DAC) member	No	No

* For NAFDAC: as detailed in [directive on reliance](#) of 28th Aug 2025

Regulatory considerations: product registration



1.Regulatory stakeholders		
NRA	National Agency for Food and Drug Administration and Control (NAFDAC)	Medical Laboratory Science Council of Nigeria (MLSCN)
2.Application for registration (public and private sectors)		
Guiding documents	<ul style="list-style-type: none"> Guidelines for Registration of Medical Devices in Nigeria 2025 Guidelines for Registration of Medical Devices Including IVDs Under WHO CRP (Apr 2025) 	<ul style="list-style-type: none"> Laboratory Handbook (MLSCN/IVD/HB/196 V-002) Federal gazette no 123: In-vitro diagnostics (IVDs) Regulations (2021)
Application portal	NAMAPS	www.mlscn.gov.ng/ivd
Language	English	English
3.Registration approval timeline		
Regular review	120 days (class A) 240 days (class B,C, D)	Product listing within 4 months (including 14 days for Dossier Review and Validation Application)
Collaborative registration	90 days	Within 90 days
Emergency Use Authorization	14 days	Not specified
4.Marketing authorization validity		
Initial	5 years (Food and Drug Registration Committee (FDRC) approval & certificate of registration)	5 years (product listing)
Renewable	yes	yes

Regulatory considerations: importation

5.Requirements for importation		
Conformity assessment	<ul style="list-style-type: none"> • ISO 13485 • GMP Inspection • Laboratory testing • Submission of technical Documents 	<ul style="list-style-type: none"> • National Guidelines and ISO 13485; ISO 14971, CLSI Guidelines • Import permit • Dossier Document Review • IVD Product Analytical Testing for performance characteristics • Listing Certificate
Guiding documents	<ul style="list-style-type: none"> • NAFDAC Guidelines for Conformity Assessment of In Vitro Diagnostic (IVD) Medical Devices 2024 • Guidelines for Registration of Medical Devices Including IVDs and Related Products (Step II, 5.0) • Guidelines For Clearing of Imported ...Medical Devices At Ports Of Entry in Nigeria 	<ul style="list-style-type: none"> • Laboratory Handbook (MLSCN/IVD/HB/196 V-002) • Federal gazette no 123: In-vitro diagnostics (IVDs) Regulations (2021)
Temporary import mechanism	Import Permit for registration samples for laboratory testing /evaluation	Provisional import Permit for pre-market IVD product validation
Authorized party	<ul style="list-style-type: none"> • Local representative with power of attorney 	<ul style="list-style-type: none"> • Local licensed manufacturer, distributor, importer • Certificate issued within 1 month, valid 1 year • https://portal.mlscn.gov.ng/ • Repository of approved IVDs providers
Additional	<ul style="list-style-type: none"> • Importer of testing devices and equipment must register with the Standards organization of Nigeria (SON) and complete all relevant steps of the SONCAP pre-shipment verification of conformity program 	

Enablers	Barriers
<p>NAFDAC:</p> <ul style="list-style-type: none">• Efforts for regulatory harmonization & streamlining of approval pathway<ul style="list-style-type: none">• IMDRF and ICH member• WHO GBT maturity level 3 NRA• Early implementer of WHO GBT plus Medical Devices and IVDs: 1st benchmarking in Nov 2024, 2nd in Aug 2025 and 3rd one underway at the time of country consultation) <p>MLSCN:</p> <ul style="list-style-type: none">• MoU between MLSCN and WHO-CRP for abridged review• MoU with as IVD testing facilities across the 6 geo-political zones for premarket validation	<ul style="list-style-type: none">• Limited funding for operations• Uncertainty and administrative burden for manufacturers due to:<ul style="list-style-type: none">• Parallel registration pathways (NFADAC and MLSCN)• Additional requirements from SON for imported testing devices and equipment

Uptake in national policy	
Evidence generation (pre-market)	Pre-market validation/verification conducted by MLSCN under Nigeria National Accreditation System (NiNAS) ISO/IEC 17025:2017. SONCAP also involved.
Verification	NTBLCP Quality Assurance team assesses laboratory performance characteristics of incoming kit lots before deployment.
Review of evidence	<ul style="list-style-type: none"> • Lead: Nigeria NTBLCP, under the oversight of the FMoH and the Department of Public Health. • Coordination with: <ul style="list-style-type: none"> • State TB Programs • National reference laboratories • Technical working groups (e.g.: the TB Laboratory TWG, the National Laboratory Technical Working Group (NLTWG), PMDT committee etc.)
Key stakeholders	<ul style="list-style-type: none"> ▪ NAFDAC and MLSCN (regulation) ▪ WHO country office ▪ Global Fund, USAID and CDC/PEPFAR (funding) ▪ Technical/implementing partners (e.g., IHVN, KNCV Nigeria and international, CHAI, MSH, Damien Foundation etc.) ▪ Civil society/Community based organizations ▪ Research/academic institutions

Enablers	Barriers
<ul style="list-style-type: none">• NTBLCP/NSP openness to innovation aiming to increase access and coverage in decentralized settings.• Established frameworks and guidelines for the validation of IVDs (MLSCN and NTBLCP).• Dynamic research ecosystem (e.g. IHVN, KNCV Nigeria, Zankli Research Center, Jana Health Foundation etc.) to conduct operational and implementation studies informing NTBLCP strategic and operational planning.• A National Essential Diagnostics List (NEDL) facilitates integration into national policy and placement of new tools.	<ul style="list-style-type: none">• Potential for overlap between MLSCN and NTBLCP QA team for new tests validation/verification and need for coordination.• Updates to NTBLCP policies and guideline tied to scheduled expert reviews, meetings and printing cycles may cause delays.



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Key findings

Pricing, procurement and supply chain

Procurement and supply chain considerations

WHO PQ/recommendation



Importation

- Duty waiver (MoF)
- Regulatory approval or waiver (NAFDAC /MLSCN)
- Import license & certificates (NAFDAC, SONCAP)

Pilot phase

- Test evaluation (academia) or verification (NTBLCP QA team)
- Pilot report

Policy adoption

- Revised algorithm
- Determination of placement location/target

Supply plan & procurement

- Quantification (holistic for old and new tools to avoid disruption)
- Supply plan update (Oct & March of each year)
- Resources mobilization
- Procurement



Implementation and scale up

Financing and pricing	
Funding for TB control activities (in 2024, WHO TB data hub)	<ul style="list-style-type: none">• 18% domestic funds (USD 20 million)• 22% from USAID (USD 25 million)• 60% Global Fund (USD 69 million) with a 73 % budget gap ~90% of TB lab instruments and commodities procured through the Global Fund grant (at time of the country consultation)
Procurement platforms	<ul style="list-style-type: none">• Global Drug Facility (GDF) with lag time of 3-5 months from order to delivery• WAMBO with lag time of 8 months from order to delivery
Other potential sources of funding (domestic)	<ul style="list-style-type: none">• The National Health Insurance Scheme (NHIS) under the NHIA• The Basic Healthcare Provision Fund (BHCPF)

Enablers	Barriers
<ul style="list-style-type: none">• Listing of the MiniDock MTB test by the expert review panel for diagnostics (ERPD) for procurement eligibility in July 2025 and Nigeria inclusion in the Global Fund near POC access fund allowing pilot roll-out in 2026• Global fund support for expansion of the NHIS in 5 states during Grant Cycle 7 to inform nationwide scale up.	<ul style="list-style-type: none">• Over-reliance on external funding and limited domestic budget allocation (only 4.8% in 2024*)• Delays in donor disbursements & operational cash flow problems leading to procurement delays & commodities stock outs (ie: Truenat reagents stockouts from Jan-March 2023).• Fluctuations in local currency/inflation negatively impacting the supply chain (both procurement & distribution).• Long lead times from ordering to receipt with need for robust advanced planning• Low coverage of the NHIS (only 5% of the population enrolled) and high out of pocket expenditures for TB services

* [WHO TB data hub](#)



Key findings

Use case(s), implementation & scale up

According to TB NSP (2021-26) emphasis is on **potential to meet the need**

- The target for access to mWRD is 1 per 175,000 population.
- Currently **1,162 mWRD have been deployed** (inc.: 513 GeneXperts, 277 TB-LAMP & 372 Truenat)
- **Current gap** to increase access is therefore **200 mWRD** (based on a population estimate of 230 million) to be positioned at PHC level & in hard-to-reach areas.

Anticipated Use Case(s)	
Swab based portable molecular test	complement/replace other molecular WRDs for rapid case detection (inc. capacity for DTS as applicable) support active case-finding initiatives in high-risk groups and settings (outreach in communities, prisons, miners, high-risk groups /PLHIV/contact case investigations)
Next generation LAM (use irrespective of HIV status)	expanded the use of the test, especially for active case finding at primary health care /ART sites



Prioritization criteria for new TB Dx tools

- **Value for money from a system perspective**, i.e. taking into consideration recurring costs for consumables, maintenance, logistics & operations in addition to upfront investment for purchase of the equipment.
- **Good analytical performance**
- Potential for **use with a variety of samples and in different populations**
- Potential for **multiplexing and integration** in existing network.
- **Heat stability** of equipment and reagents (i.e.: local temperatures can reach up to 45°C).
- Ability for deployment in hard-to-reach areas (**portable**) and to **function off grid**.
- **Minimal biosafety** (containment) requirements.
- **Minimal waste and environmental footprint**.
- **User-friendliness** (i.e.: few handling steps), to enable non-lab-trained staff to use components and **potential for task shifting for use at community level**.
- **Capacity to test resistance to new drugs as they enter the market**

Implementation: key steps



Timelines for early uptake: 6 months - 1 year

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 sensitization	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

Implementation: cross cutting systems challenges



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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)

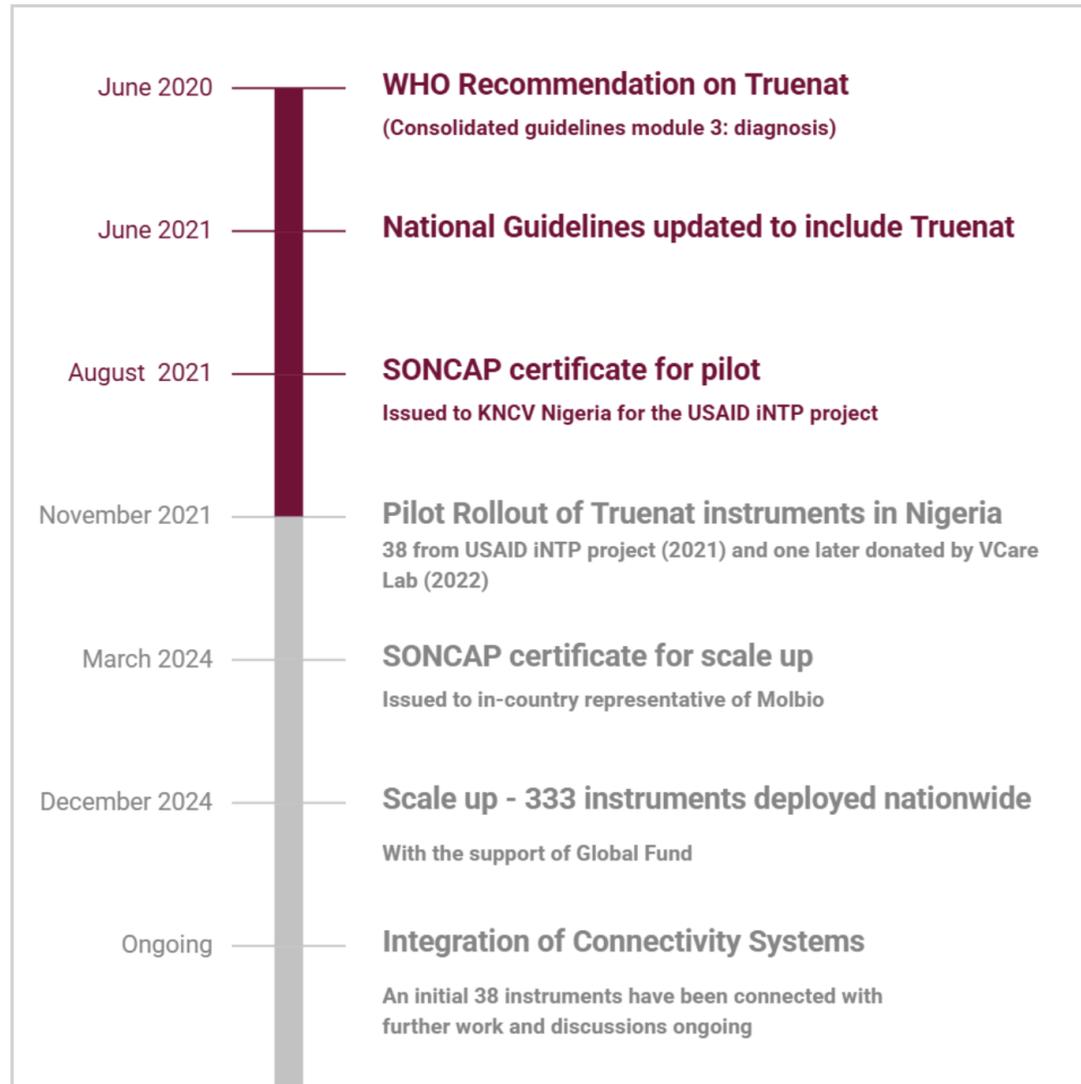
Challenges	Number of institutions (n=62)
Absence of POC diagnostic tests with special software to help imaging interpretation	39 (62.9)
Inefficient Procurement System	38 (61.3)
Frequent Stockouts	37 (59.7)
Lack of funds for transportation & costs of additional diagnostics	37 (59.7)
Limited Access to 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)

Extracted from : *Nigeria National Essential Diagnostics List*. FMOH. May 2022 (Table 4, page 55)

Scale up considerations

Scale up	
Maintenance	<p>Per Nigeria Bureau for Public Procurement:</p> <ul style="list-style-type: none">Manufacturers and suppliers of health and medical equipment (must) 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.
EQA	<p>The National Quality Assurance (QA) Team coordinates EQA during deployment and scale up of new diagnostic tools:</p> <ul style="list-style-type: none">The NRL validates and evaluates diagnostic protocols, prepares EQA panels, and provides technical assistance.Zonal and State TB Reference Laboratories support oversight, panel distribution, and supervisionEQA performance monitored through biannual panel testing and quarterly on-site evaluations
TB-LIS	<p>National Electronic TB Information Management System (NETIMS):</p> <ul style="list-style-type: none">eTB manager is the national TB case notification systemthe laboratory network relies mostly on GxAlert as a connectivity solution (need to ensure LIS captures also results from near POC tests)

Historical timelines: Truenat assay



Recommendation for Truenat was included in WHO guidelines in June 2020

 Inclusion into policy: 1 year

 National policy to pilot: 5 months

 National policy to scale up: 3 years

 Access, overall: **4 years**

Enablers	Barriers
<ul style="list-style-type: none">• Committed governance and leadership and availability of national strategic & operational plans, with a National Essential Diagnostics List (NEDL) that includes TB diagnostics.• Donors' support for pilot introduction of new tools (e.g. USAID/Stop TB Introducing New Tools project, Global fund grant for scale up of Truenat and LAMP assays, UNITAID for LAM, etc).• Country's intention to allocate USD 54 million from its domestic resources to purchase TB drugs and diagnostics through the Global Drug Facility.• In country representation and service centers from major manufacturers (e.g. Cepheid, Molbio, etc) collaborating with NTBLCP.	<ul style="list-style-type: none">• Cross cutting systemic challenges• Limited in-country capacity to sustain and expand externally funded pilot projects for new TB diagnostics• Limited access to TB services in the country & poor integration/ synergy of TB services with other relevant sectors.• Incomplete scale-up of the TB LIS and limited coverage of electronic data systems at facility level, with reliance on third-party developers.



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Key findings

Demand creation and advocacy

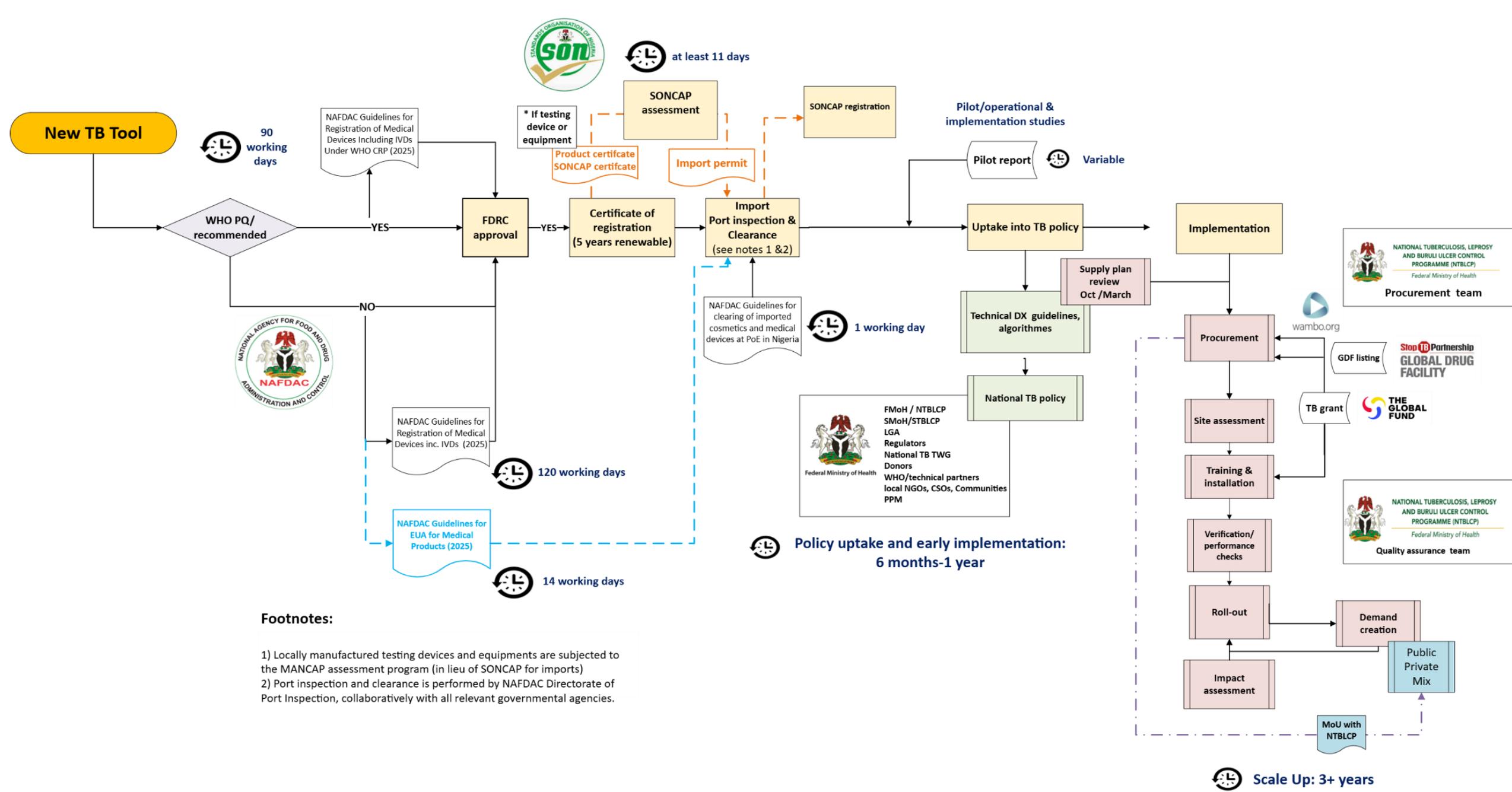
	Stakeholders	Activities
National	Government Bodies NTBLCP, NASCP, NACA, NCDC, NPHCDA, Stop TB Partnership, Implementing Partners (KNCV, IHVN), Office of the First Lady	Established outreach days - World TB Day, World AIDS Day, National Testing Week, RMNCH week, etc. Press Releases, Briefings, Field Activities
	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

Enablers	Barriers
<ul style="list-style-type: none">• High-level political support from the First Lady and Governors' Wives as TB Ambassadors• A successful PPM model and targeted outreach strategies expand access for vulnerable populations with financial support from funders (Global Fund, USAID, TB Reach etc.) and implementing partners• Media support and health promotion of new diagnostics at the national, subnational and community levels• National conferences (e.g: Stop TB Partnership Nigeria) and communities of practice (ie: ASLM LabCop) for awareness rising.	<ul style="list-style-type: none">• Superstitious beliefs, myths and misconceptions, fear of discrimination• Limited awareness/Negative Mindset/Resistance to change - uptake of newer diagnostics• Limited media and health promotion interventions• Security challenges• 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



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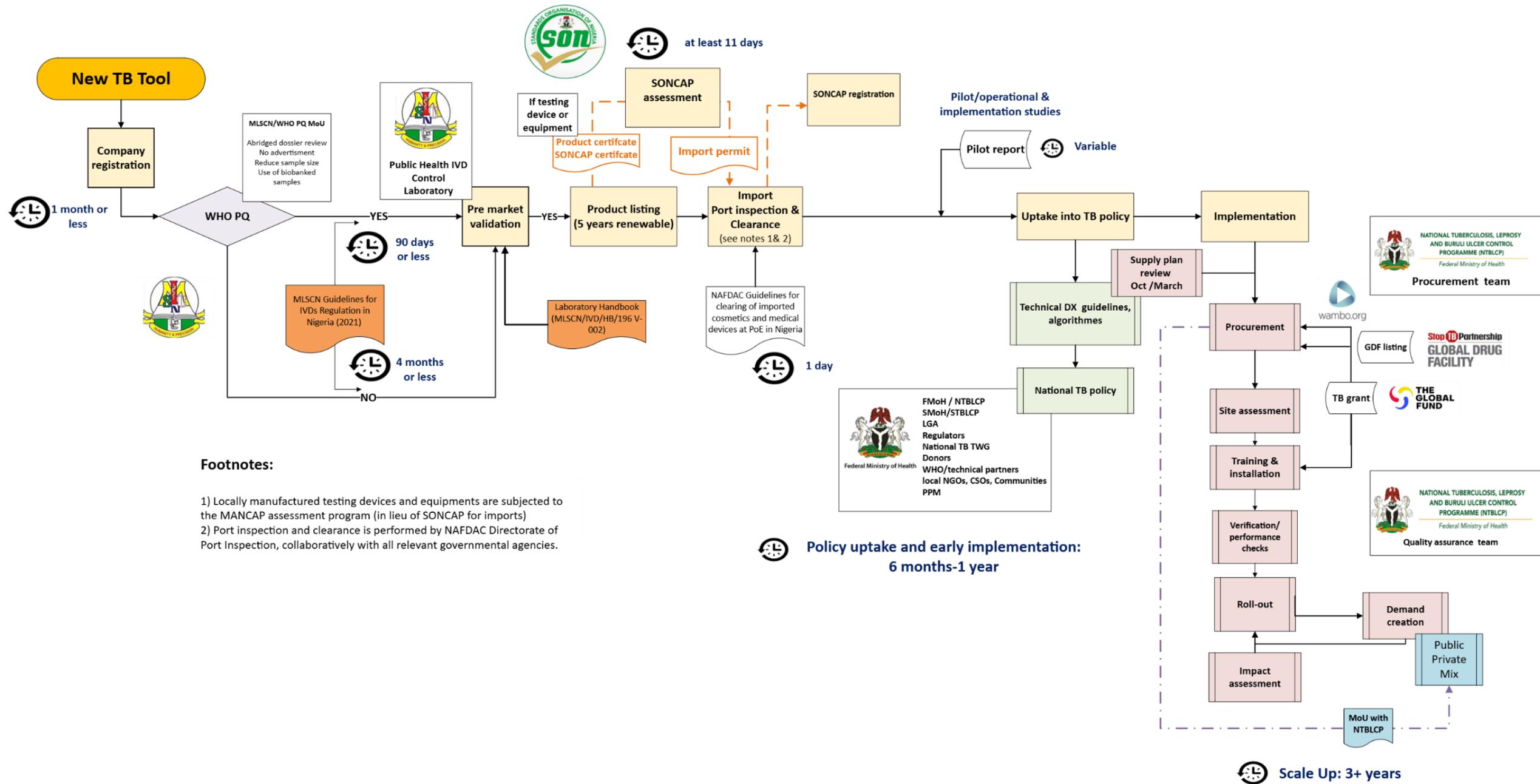
Country CPA roadmaps



Footnotes:

- 1) Locally manufactured testing devices and equipments are subjected to the MANCAP assessment program (in lieu of SONCAP for imports)
- 2) Port inspection and clearance is performed by NAFDAC Directorate of Port Inspection, collaboratively with all relevant governmental agencies.

Figure 6: Roadmap for introduction of new TB diagnostics in the public and private sectors (NAFDAC entry)



Footnotes:

- 1) Locally manufactured testing devices and equipments are subjected to the MANCAP assessment program (in lieu of SONCAP for imports)
- 2) Port inspection and clearance is performed by NAFDAC Directorate of Port Inspection, collaboratively with all relevant governmental agencies.

Figure 7: Roadmap for introduction of new TB diagnostics in the public and private sectors (MLSCN entry)



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Recommendations



FMoH/SMoH/NTBLCP/TB NRL	National regulators (NAFDAC, MLSCN, SON)	Partners & donors	Manufacturers
<ul style="list-style-type: none">• Develop a priority plan to transition lab system strengthening from external to domestic funding, including clear KPIs, targets, and timelines.• Include TB diagnostics services in NHIS/BHCP to reduce out of pocket expenditures.• Ensure timely implementation of the pilot roll out of the MiniDock MTB.• Mobilize (domestic) funding for CHWS.• 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.	<ul style="list-style-type: none">• Clarify and connect potentially duplicative processes to reduce confusion, administrative and financial burden for manufacturers.• Publish the listing of registered medical devices and IVDs (i.e.: online).• Advocate for ratification of the African Medicines Agency treaty and align with regional initiatives to accelerate diagnostic products introduction• Pursue efforts for strengthening national regulation for medical devices and IVDs (WHO GBT)	<p>WHO / PQ teams and continental regulators:</p> <ul style="list-style-type: none">• Expedite the review of evidence and publication of policy recommendations for novel diagnostics• Ensure collaboration & synergies <p>Donors:</p> <ul style="list-style-type: none">• Incorporate cost-effectiveness analysis into market shaping initiatives. <p>In country partners /CSOs :</p> <ul style="list-style-type: none">• Maintain support for operational research informing optimal tool introduction.• Support community-led monitoring to strengthen advocacy and feedback mechanisms for improved diagnostic service delivery.	<ul style="list-style-type: none">• Ensure dossier completeness per NAFDAC, MLSCN, and SON guidelines.• Ensure full registration for devices and IVDs introduced through waivers, as per national guidelines.• Leverage in-country technical expertise for pre-registration performance evaluation..



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