Lab CoP

ASLM

RECIPE #10:

INTEGRATING PRIVATE MEDICAL LABORATORIES INTO NATIONAL LABORATORY NETWORKS:

A PRACTICAL GUIDE

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

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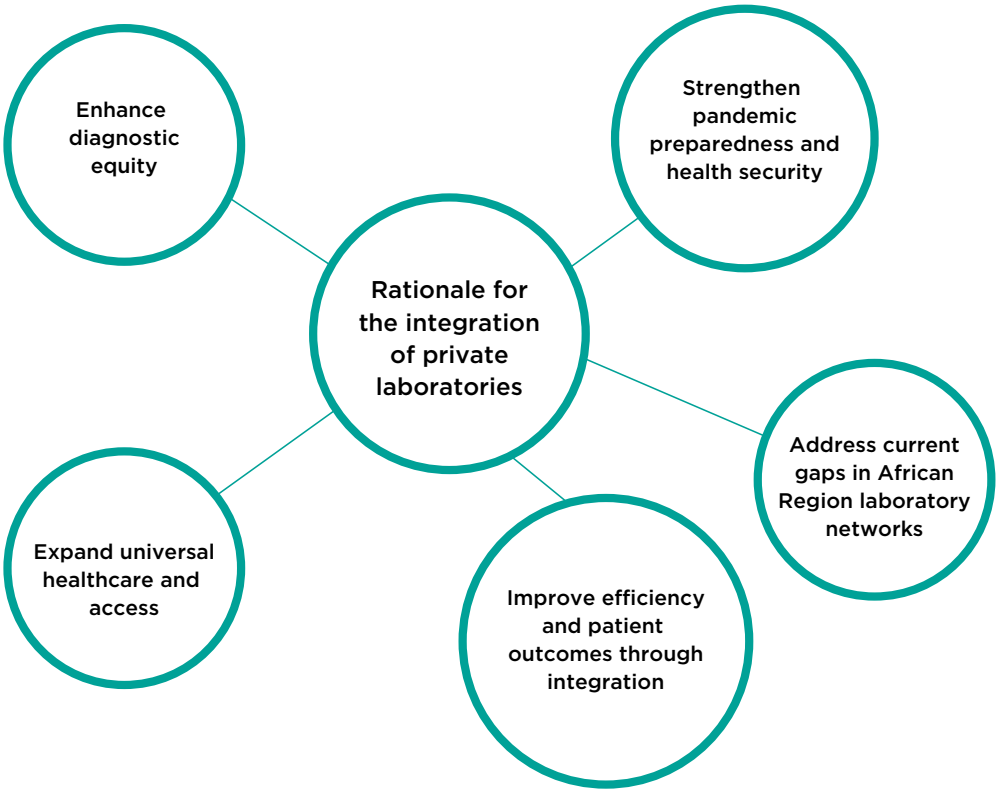
INTRODUCTION

The integration of private medical laboratories into national laboratory networks is critical for achieving diagnostic equity, strengthening pandemic preparedness, and advancing global health security. In many low- and middle-income countries (LMICs), private laboratories comprise a significant proportion of diagnostic capacity, yet they remain excluded from national systems that govern disease surveillance, quality oversight, and health data reporting.[1-3] This gap results in missed opportunities for real-time outbreak detection, leads to fragmented responses and duplicative testing, and contributes to inequitable access to timely diagnostics.

The effective integration of medical laboratories promotes real-time data sharing, reduces the time from sample submission to the return of test results, and ensures the accuracy and consistency of tests. For example, integrated laboratory information systems (LISs) in Uganda have substantially reduced diagnostic turnaround times through electronic results dispatch and workflow optimisation.[4, 5] At a global level, harmonised public-private response strategies have increased TB case detection by two- to four-fold in several settings.[6] Moreover, integrating private laboratories with national laboratory networks supports compliance with International Health Regulations by ensuring all diagnostic providers contribute to core surveillance capacities.[7] It also underpins universal health coverage by broadening access to quality-assured diagnostics,[8] particularly in underserved urban and peri-urban areas where private laboratories are concentrated.

The integration of private and national laboratories is also vital to ensure compliance with regulatory, quality assurance, and data-reporting standards. Without integration, the oversight of private medical laboratories often remains minimal or fragmented. National laboratory directorates typically have limited visibility over private diagnostic operations, with engagement occurring mainly through initial licensing or periodic registration managed by professional councils or regulatory authorities. Once licensed, many private laboratories operate outside the quality assurance, surveillance, and data-reporting frameworks that govern public facilities. This regulatory gap means that laboratory directorates cannot systematically monitor test quality, diagnostic coverage, or compliance with national disease-reporting obligations. As a result, a substantial proportion of the diagnostic data generated in the private sector never reaches national health information systems, constraining situational awareness, outbreak detection, and evidence-based planning. These gaps could be addressed by mandating that private laboratories submit and report data to national laboratory networks and comply with supervision and quality monitoring. For these reasons, integrating private laboratories into national laboratory networks is central to building a unified and resilient laboratory network (Figure 1).

Figure 1. Rationale for the integration of private laboratories into national laboratory networks

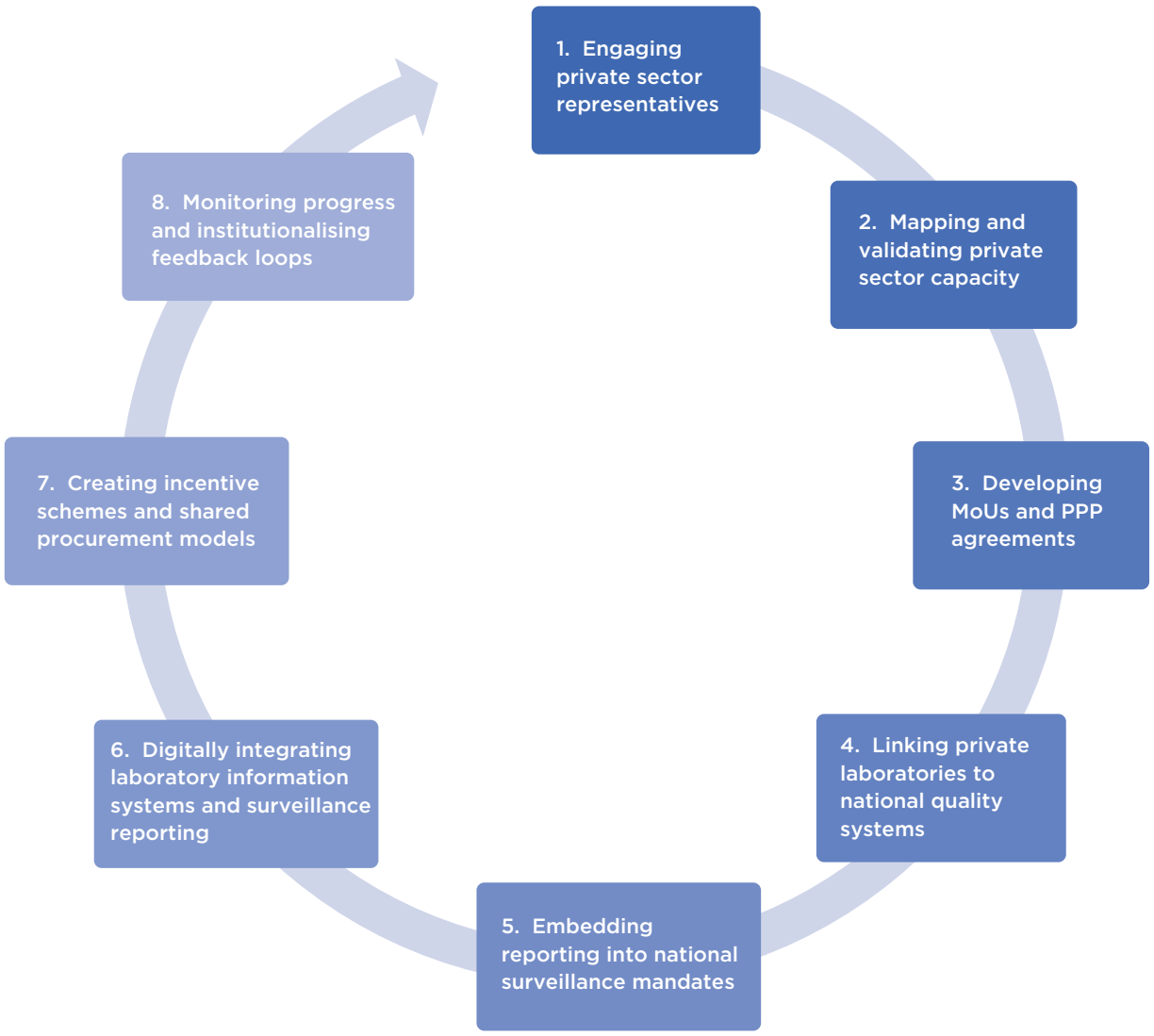


In the African context, where health system constraints are acute and laboratory infrastructure is unevenly distributed, leveraging private sector capacity is indispensable. This recipe provides a practical, step-by-step guide to help Ministries of Health (MoHs) and national laboratory programmes rapidly and effectively integrate private laboratories into public diagnostic systems. The approach leverages existing structures – such as policies, technical working groups (TWGs), LISs, external quality assessment (EQA) systems, and surveillance platforms – and outlines how these can be adapted to embrace private sector participation. This recipe synthesises lessons from ASLM's LabCoP* Extended ECHO sessions, legal frameworks, and country experiences to provide an actionable roadmap for MoHs and national laboratory programmes.

The recipe comprises eight key steps to support the integration of private sector laboratories into national laboratory networks, as outlined in Figure 2. The sections outline the aims, importance, key considerations and best practices of each step, drawing on practical examples from across African countries.

* LabCoP: Laboratory Systems Strengthening Community of Practice.

Figure 2. Process for the sustainable and scalable integration of private sector laboratories into national laboratory networks



STEP 1:

ENGAGING PRIVATE SECTOR REPRESENTATIVES IN EXISTING TECHNICAL WORKING GROUPS AND NATIONAL COMMITTEES

AIM:

Establish trust and shared governance by involving private laboratory leaders in joint decision-making.

WHY IT IS IMPORTANT:

Mistrust between public and private sectors hinders data sharing and cooperation. Early engagement builds buy in and ensures that policies reflect practical realities. Inclusive committees reduce resistance when new reporting mandates and other collaborative facets are introduced.

A foundational step towards integrating private medical laboratories into national laboratory networks is to institutionalise their participation in existing policy, technical, and coordination platforms. Most LMICs already maintain TWGs, Laboratory Policy Committees, and National Disease Programme Task Forces – particularly for vertical programmes like HIV, tuberculosis (TB), malaria, and antimicrobial resistance (AMR). However, these bodies are often composed exclusively of public sector stakeholders. This results in policy decisions that fail to reflect the capacity, challenges, and perspectives of the private diagnostic sector, which may account for over 60% of diagnostic services in urban centres.

KEY CONSIDERATIONS

Effective integration requires moving from a top-down consultative approach to a shared governance model that includes private laboratories in the design, implementation, and oversight of national diagnostic strategies. Representation in TWGs and policy committees not only ensures inclusivity but also facilitates transparency, joint planning, and mutual accountability. In this context, a key consideration is the importance of shared governance as the starting point for building trust and legitimising public-private partnerships (PPPs) in laboratory governance.

Key considerations for action:

- Map existing TWGs, laboratory committees and disease programme task forces and identify gaps in private sector representation.
- Review the terms of reference for each TWG to allow private participation and issue a policy memo inviting recognised private laboratory associations to nominate delegates.
- Vet nominees, provide onboarding on national laboratory strategy, and document participation in meeting minutes and reports.
- Evaluate the effectiveness of engagement after 6 to 12 months.

BEST PRACTICES

There are several best practices for engaging private sector representatives in TWGs and national committees. Key among these is ensuring that the inclusion of private sector representatives is formalised and not just symbolic, by revising membership terms of reference (ToR), meeting structures, and reporting protocols. Expanding the membership of existing TWGs and disease programme committees to formally include private sector laboratory stakeholders must also ensure that private sector stakeholders have a voice in decision-making processes.

To start with, countries (ideally the MoH Diagnostics Directorate) should map existing TWGs, laboratory committees and disease programme task forces to identify all relevant stakeholders for the exercise. Next, the ToR for each TWG should be reviewed to assess whether private sector stakeholders are eligible to participate in the group. Subsequently, a formal policy memo should be drafted, inviting private sector laboratory associations to nominate representatives to participate in the TWG. Invitations should then be sent to recognised private laboratory associations and networks. The CVs of proposed delegates should be collected, with proposed delegates vetted and confirmed through existing TWG mechanisms. Following confirmation of the delegates, onboarding meetings should be held for new members, covering the TWG scope, national laboratory strategy and reporting structure. The participation of private sector delegates should be documented in official minutes and TWG reports. Private sector representatives should be included in all subsequent meetings and planning cycles. The effectiveness of engaging the private sector representatives in TWGs and national committees should be evaluated after 6 to 12 months.

Specific best practices include:

1. **Establish an MoH-led nomination process.**
   Issue an official circular or policy memorandum from the MoH (or National Public Health Institute) inviting recognised private laboratory associations, hospital consortia, or accredited private laboratory networks to nominate 1–2 representatives per TWG. Ensure that interest groups and technical competence are considered in the selection.

   In Ghana and Nigeria, the MoH and National Public Health Laboratory expanded the National Laboratory Technical Committee to include private laboratory stakeholders. Through this, private laboratories were actively involved in planning for HIV viral load testing scale-up. As a result, HIV case reporting improved by over 40%, turnaround time for referrals decreased, and reporting compliance among private facilities significantly increased.

2. **Revise the ToR to specify the roles of private sector laboratory representatives.**
   Update the ToR of each TWG to formally define the role of private sector laboratory representatives, including their responsibilities in policy reviews, data reporting, and quality assurance oversight.

3. **Undertake orientation and alignment.**
   Organise an onboarding session for new private sector members to understand national priorities, existing diagnostic frameworks, and expectations. This helps ensure productive participation from the start.

   In Kenya, public-private mix (PPM) activities have been undertaken to strengthen TB case finding and quality of care. As part of these efforts in 2023, 4326 private facilities were mapped, with 2715 of these facilities signing formal Memoranda of Understanding (MoUs) to provide TB services, and 2197

of the facilities consistently reporting TB services over the year.[9] *Data bundles were also provided to 2142 facilities to strengthen the reporting of PPM data. Additionally, 647 healthcare workers from private facilities were trained on TB, and 97 motorcycle riders were supported to strengthen sample referral networks and ensure the linkage of private facilities to TB diagnostic sites.*[9] *Incentive payments of 1000 Kenyan shillings (KSh) per TB case successfully identified and linked to treatment were offered for 11,968 TB cases successfully notified from private facilities.9 Furthermore, 175 PPM TWG meetings were held across 46 counties in 2023.*[9] *These approaches – bringing private leaders into decision-making, backing engagement with training, reporting subsidies, and logistics support – have enabled the translation of policy into measurable increases in notifications from the private sector.*

4. **Start with high-impact areas.**
Begin with TWGs for HIV, TB, malaria, and AMR – where diagnostic volume and epidemiological risk are high – and gradually scale to other disease programmes and cross-cutting platforms (e.g., digital health, supply chain).

STEP 2:

MAPPING AND VALIDATING PRIVATE SECTOR CAPACITY

AIM:

Obtain a complete, accurate picture of private laboratory locations, test menus, volumes and quality credentials.

WHY IT IS IMPORTANT:

Ministries cannot manage what they cannot measure. Mapping reveals service gaps, duplication and potential partners. Further, it forms the foundation for accreditation, digital connectivity and resource planning. A well-executed mapping and validation exercise provides the foundation for PPPs, targeted investments, coordinated surveillance, and scalable policy implementation. It also enables MoHs to identify laboratories eligible for EQA, accreditation support, and inclusion in disease control programmes (HIV, TB, malaria, AMR etc.).

One of the critical early steps in integrating private laboratories into national diagnostic networks is gaining a clear, current, and comprehensive picture of the private diagnostic landscape. In many countries, health authorities lack a validated database of private medical laboratories, their location, what services they offer, their diagnostic volumes, and their quality credentials. This data vacuum hinders effective planning, quality oversight, surveillance integration, and the allocation of resources.

KEY CONSIDERATIONS

A key consideration is the need for a standardised and well-defined approach to mapping private laboratories, including agreed indicators and tools to reliably capture information on their capacity, quality systems, and regulatory status. To guide the mapping and validation exercises, the MoH Laboratory Directorate could consider developing a private laboratory mapping protocol to define the methodology, indicators and expected outcomes. Subsequently, the Surveillance or Monitoring and Evaluation unit could develop or adapt an existing mapping tool to capture the required information on private sector capacity. This tool could capture features such as the test menu, EQA, LIS, and licensing status. The mapping tool could be disseminated across regions to ensure its use.

Countries could also consider offering training to regional data collectors on mapping procedures, to ensure the tool is appropriately used. Consideration should be given to facilitating a standardised approach to data collection and validation, for example through using site visits or phone calls for data validation. It is also important that countries have processes to clean and harmonise datasets to ensure usable and accurate data. In the data analysis phase, laboratories could be classified by tier and readiness level, using a defined scoring system. Countries could also consider how summary statistics will be displayed and consider the development of a dashboard to display laboratory distribution and gaps. Finally, findings can be disseminated with key stakeholders via reports, presentations, and TWG briefings.

Key considerations for action:

- Develop a mapping protocol defining indicators and expected outputs, and adapt a data collection tool to capture features such as laboratory GPS coordinates, ownership, test menu, equipment, and accreditation status, among others.
- Train regional officers and disseminate the tool nationally; use the data collection tool to collect data via site visits or phone interviews.
- Validate submitted data through follow-up calls or inspections, then clean and harmonise the national database.
- Classify laboratories by complexity aligned to the public sector tiering system, and develop dashboards showing geographic distribution and service gaps.

BEST PRACTICES

As best practice, countries should conduct a national mapping exercise to identify, register, and classify private sector laboratories operating within the country. This exercise should go beyond simple enumeration and include essential operational and quality parameters, enabling policymakers and regulators to make evidence-based decisions. Key steps as part of this exercise should include:

1. **Develop or adapt a standardised mapping tool.**

Leverage existing mapping tools (e.g. LabMap[10]) to capture core variables such as:

- legal name and address of the laboratory
- geolocation (GPS coordinates)
- ownership type (individual, hospital-based, chain network, non-governmental organisation)
- test menu (e.g., HIV, TB, malaria, non-communicable diseases)
- monthly or annual sample volumes
- equipment and LIS status
- participation in EQA or accreditation programmes
- regulatory licensing status
- staff qualifications and Continuing Professional Development records.

2. **Roll out mapping at a national scale efficiently by leveraging existing modalities and infrastructure.**
   Work through regional or district health teams to distribute and administer the tool. Consider mixed modalities: online submission (Google Forms, SurveyCTO), physical forms for low-connectivity areas, and integration with existing health facility assessments (e.g., Service availability and readiness assessment [SARA], Stepwise Laboratory Quality Improvement Process Towards Accreditation [SLIPTA] baselines).[11, 12]

   In South Africa, the National Health Laboratory Service developed a national registry of private laboratories, classifying them by services provided, location, and performance metrics. This registry informed procurement decisions, guided quality assurance expansion, and served as the foundation for PPP contracts across the TB and HIV diagnostic continuum. As a result, the National Health Laboratory Service increased the reach of its testing programmes into underserved provinces and improved surveillance data harmonisation.

3. **Validate and classify.**
   Conduct desk reviews and field verification of data where needed. Partner with professional councils or health facility regulatory agencies to cross-reference submissions. Classify laboratories into tiers based on service complexity, volume, and readiness for PPP engagement.

In Nigeria, the Medical Laboratory Science Council requires laboratories seeking registration to submit a floor plan, equipment lists, organisational charts, test menus and a quality manual – providing national oversight of the country's medical laboratories.[13, 14] Nigeria's private laboratory capacity grew substantially during the COVID-19 pandemic, expanding from 3 laboratories in February 2020 to 84 government laboratories, 58 private laboratories and eight corporate laboratories by September 2021.[15] Similarly, COVID-19 testing capacity increased from an average of 2500 samples per day in April 2020 to 5250 samples per day a year later.[16] Mapping remains relevant beyond COVID-19: a recent analysis of TB notifications shows that cases in Nigeria increased from 58,219 in 2021 to 108,530 in 2023 – an 86.5 % rise – while the private sector's share of notifications increased slightly from 28% to 29% during the same time period.[17] The number of GeneXpert machines installed in the private sector almost doubled from 49 in 2021 to 92 in 2023, an 88% increase, and private Xpert sites performed an average of 12 tests per day compared with eight in public facilities.[17] Accurate mapping tools are therefore essential to capture rapid growth in private laboratories, track new technologies and avoid duplication of services.

4. **Develop a digital registry or dashboard.**
Compile the data into a centralised database or GIS-enabled dashboard. Make summary statistics available to key stakeholders (e.g., MoH, national programmes, implementing partners) for planning and follow-up.

STEP 3:

DEVELOPING MEMORANDA OF UNDERSTANDING AND PUBLIC-PRIVATE PARTNERSHIP AGREEMENTS

AIM:

Provide a common understanding and alignment of goals and collaborative roles between the private sector and national diagnostic network. Additionally, provide legal certainty for public and private partners by clarifying roles, responsibilities, financing mechanisms and dispute resolution processes.

WHY IT IS IMPORTANT:

Informal relationships can lead to misunderstandings about obligations and expectations. In contrast, written agreements promote accountability and sustainability. Integrating private medical laboratories into national diagnostic systems requires a formal, structured, and enforceable partnership framework. MoUs and PPP agreements serve as legal and operational tools to define expectations, delineate roles, and create accountability for both public authorities and private sector laboratories.

Without MoUs, partnerships often remain informal and fragile, leading to unclear roles, inconsistent data sharing, and lack of consequences for underperformance. A well-crafted MoU is a catalyst for trust, coordination, and sustainability. When designed with care, these agreements incentivise private laboratories to align with national priorities such as disease surveillance, quality improvement, and real-time reporting.

KEY CONSIDERATIONS

Developing an MoU for private sector laboratory partnerships starts with drafting a standardised MoU template, which outlines the scope, responsibilities, incentives, penalties and duration of the agreement. This template should ideally be drafted by the MoH Legal and PPP units or their equivalents. The MoU could be reviewed by private sector stakeholders and endorsed by the country's Ministry of Justice or Health Legal Affairs department, to ensure it is legally binding and compliant with national laws. The MoU template could subsequently be disseminated to eligible laboratories for review, via official channels and during PPP forums. A set of suitable private laboratories could be selected as a pilot group to sign the MoU. Ideal pilot laboratories are those already active in TB/HIV diagnostics or those with demonstrated capacity in these areas. An official MoU signing event or remote endorsement could subsequently be organised for the pilot group. Following the joint signing of the MoU, the implementation of the MoU and adherence to its terms could be monitored in accordance with pre-determined measures (such as whether laboratories are accredited, have EQA in place, and are reporting data according to standards). Countries can consider amending or renewing MoUs as necessary, based on annual performance or programmatic changes.

Key considerations for action:

- Draft a standard MoU or PPP agreement that spells out joint responsibilities, financing (fee for service, performance-based incentives or subsidies), data sharing provisions, confidentiality and dispute resolution.
- Align MoUs with national PPP legislation and procurement laws and include clauses on quality management, EQA participation, reporting and staff training.
- Use national PPP units or legal departments to vet agreements and ensure enforceability.

BEST PRACTICES

As best practice, countries should develop and sign standardised, rapidly deployable MoUs or PPP agreements with private laboratory stakeholders at national, regional, or programme-specific levels. These agreements should clearly define responsibilities, incentives, and accountability mechanisms to ensure mutual benefits and alignment with public health goals. Key steps include:

1. **Draft a standardised MoU template.** Create a reusable MoU template vetted by the MoH's legal and PPP units (See Annex 1). This should cover:

- **Scope of services:** e.g., provision of HIV viral load testing, TB GeneXpert, COVID-19 polymerase chain reaction (PCR) testing, or AMR surveillance.
- **Data-sharing obligations:** e.g., integration into DHIS2/ Health Management Information System (HMIS), monthly reporting schedules, and outbreak alerts.
- **Quality assurance commitments:** e.g., mandatory EQA participation, internal audits, and adherence to standard operating procedures (SOPs).
- **Capacity support:** e.g., access to training, SOPs, mentorship, or LIS tools from public sector programmes.
- **Incentives:** e.g., eligibility for reagent procurement, tax benefits, inclusion in national directories.
- **Enforcement measures:** e.g., consequences for non-compliance, such as withdrawal of access to national programmes or public referrals.

Formal agreements can clarify how public laboratories and emerging private providers will share data, logistics and emergency response provisions. In Nigeria, the Medical Laboratory Science Council of Nigeria and the Federal MoH operationalised a national MoU template to formalise partnerships with private laboratories engaged in HIV and AMR diagnostics (template provided in Annex 1). The MoU included clauses on data reporting, EQA participation, and accreditation progression. Private laboratories that signed the MoU were granted access to subsidised reagents, capacity-building programmes, and government referrals. As a result, participation in AMR surveillance increased by 55%, and EQA compliance among private laboratories improved substantially.

2. **Conduct stakeholder consultations.**
Involve private laboratory associations and programme leads in co-developing or refining the MoU clauses. Ensure alignment with national legal frameworks and public health goals.

3. **Fast-track legal review.**
Assign the final MoU draft to the MoH legal department or PPP unit for rapid endorsement. Pre-approval of the template can accelerate roll-out across multiple laboratories.

4. **Pilot and scale.**
Begin with high-priority programmes (HIV, TB, AMR) or regions with high diagnostic volumes. Capture lessons learned and iterate the template for scale-up.

In Kenya, the country's TB PPM Action Plan references the country's PPP Act and calls for formal MoUs with private diagnostic providers.[18] In Tanzania, certificates issued under the PPP framework specify the services to be offered, staffing requirements and renewal intervals. Additionally, the country's Strengthening Laboratory Management Toward Accreditation (SLMTA) programme enrolled 138 laboratories and by 2023 had seen 81 (59%) progress to the accreditation process, with 50 (62%) achieving ISO 15189 accreditation status.[19]

5. **Maintain a national MoU register.**
Keep an accessible register of all signed agreements, their terms, and renewal timelines. This enables transparency and coordination across stakeholders.

STEP 4:

LINKING PRIVATE LABORATORIES TO NATIONAL QUALITY SYSTEMS

AIM:

Ensure every laboratory – public or private – produces accurate results by adhering to national and international standards.

WHY IT IS IMPORTANT:

Inaccurate results undermine disease control efforts, waste resources and erode public trust. Accreditation to ISO 15189 standards[20] or equivalent is increasingly a prerequisite for inclusion in national networks.

Ensuring diagnostic accuracy and consistency across public and private laboratories is fundamental to safeguarding patient safety, building trust in test results, and meeting international health regulations. While many national laboratory systems have invested heavily in the development, implementation and ongoing assessment of public sector laboratory quality management systems, private laboratories often operate outside these frameworks. This results in wide performance variability, data quality concerns, and undermines national surveillance and clinical care efforts.

To address this, countries must enforce the mandatory enrollment of private laboratories into national quality systems. As a result, countries should consider the need for a matured system to monitor the quality of diagnostics at the national level. In this context, countries could consider adopting and implementing the African Union National Laboratory Quality Framework.[21] This requires both regulatory mandates and technical support to build quality capacity and close performance gaps. The goal is to create a cohesive quality ecosystem where every laboratory – public or private – meets minimum performance standards and contributes to national health outcomes.

KEY CONSIDERATIONS

As a first step to linking private laboratories to national quality systems, a key consideration is ensuring that the national laboratory policy is updated to mandate that all laboratories implement Laboratory Quality Management Systems (LQMSs). This ensures that private laboratories are legally required to enrol in national EQA schemes and other facets of LQMS implementation. Subsequently, countries could identify and prioritise private laboratories for immediate LQMS onboarding, targeting those involved in priority diagnostics (e.g., HIV, TB, malaria). The selected private laboratories could be enrolled into national EQA schemes, and provided with the necessary forms, schedules and sample distribution guidance to facilitate this process. Laboratories could be offered training on internal quality control and EQA interpretation, internal audits and risk management through webinars, on-site mentorship or workshops. Corrective action and risk management plans could be developed for underperforming laboratories, with non-conforming work used to trigger targeted support and continuous improvement. Countries can also consider developing a national dashboard to track private laboratory performance and visualise trends and the accreditation process. Support could be offered to promote readiness for accreditation, with preparatory resources offered to laboratories deemed ready for accreditation. Countries could also consider publicly recognising high-performing private laboratories, to motivate laboratories to improve their performance.

Key considerations for action:

- Mandate that all private laboratories register with the national laboratory council and initiate/strengthen LQMS implementation.

- Offer training and mentorship programmes (e.g., SLMTA/SLIPTA) to help laboratories implement quality management systems and progress toward accreditation.

- Enrol private laboratories in EQA schemes and develop corrective action and risk management plans for non-compliant facilities.

- Strengthen national laboratory quality infrastructure capacity to monitor public and private sector laboratories.

BEST PRACTICES

As part of best practices, countries should enforce LQMS development and implementation at private sector laboratories, including enrolment into national EQA schemes and accreditation readiness programmes as a precondition for formal integration. This should be embedded as a non-negotiable clause in any MoU or PPP agreement with the MoH or its diagnostic departments. Key best practices include:

1. **Make LQMS implementation mandatory.**
   Embed LQMS implementation as a requirement in all MoUs, licensing conditions, or PPP contracts. Clearly define the frequency of evaluations (e.g., quarterly), disease areas covered (e.g., HIV, TB, malaria, AMR), and minimum performance requirements.

   In Ethiopia, the MoH made EQA participation compulsory for all private laboratories offering testing for HIV, TB, and malaria. Laboratories that failed to enrol were removed from national patient referral lists.

2. **Provide training and supportive quality mentorship.**
   Offer SLIPTA, SLMTA, or ISO 15189 preparatory training tailored for private sector contexts. Use a train-the-trainer model and peer mentorship to scale up quality improvement efforts in resource-limited laboratories.

   To support mandatory participation in EQA, the Ethiopian Public Health Institute offered SLIPTA-based mentorship and periodic quality audits to private laboratories. Within 18 months, diagnostic errors in private laboratories dropped by 50%, and over 70% of laboratories reached acceptable EQA performance benchmarks.

3. **Offer compliant laboratories recognition and incentives.**
   Recognise compliant private laboratories by including them in national directories, procurement frameworks, or referral networks. Offer these laboratories reduced/subsidised accreditation fees or priority for capacity-building grants.

4. **Track and act on performance**

Use a centralised dashboard to monitor private laboratory performance. Apply corrective action and risk management plans for underperforming laboratories and suspend non-compliant laboratories from national reporting or procurement benefits following a predetermined sanction framework.

In South Africa, the National Accreditation System (SANAS) uses a staged process, with regular surveillance visits, including document review, on-site assessment, committee review and final decision to assess public and private laboratories.[22]

STEP 5:

EMBEDDING REPORTING INTO NATIONAL SURVEILLANCE MANDATES

AIM:

Make private laboratories full partners in disease surveillance by requiring mandatory timely reporting of notifiable diseases.

WHY IT IS IMPORTANT:

Without legal obligations, private laboratories may not prioritise reporting, especially when serving clients that seek confidentiality. Mandatory reporting improves incidence estimates, supports outbreak detection and informs public health interventions.

For any country striving to build a robust disease surveillance system, the completeness and accuracy of data is paramount. Yet, in many LMICs, the surveillance architecture is disproportionately reliant on the public sector – leaving out large volumes of critical diagnostic data generated by private laboratories. This omission compromises national visibility into disease trends, delays outbreak detection, and undermines the allocation of resources to disease responses.

To address this gap, private laboratories must be legally obligated to report notifiable diseases through official surveillance channels. Voluntary reporting – while a useful starting point – is not sufficient. Legal mandates serve as a foundational mechanism to ensure that private sector diagnostic data are standardised, timely, and fully integrated into national surveillance platforms such as DHIS2, Integrated Disease Surveillance and Response (IDSR), or other HMISs. Embedding reporting obligations into national legal frameworks reinforces accountability, facilitates compliance monitoring, and ensures that no diagnostic provider operates in isolation from the national public health agenda.

KEY CONSIDERATIONS

There are several key considerations for embedding reporting into national surveillance mandates. To start with, countries should consider regulations mandating that private laboratories report notifiable diseases within defined time frames. Countries could review existing public health law and laboratory regulations, to identify gaps related to mandatory disease reporting among private laboratories. Surveillance reporting clauses could be subsequently drafted, where missing from existing law and regulations. These reporting clauses could include a list of reportable diseases, timelines, formats and sanctions for non-compliance. Following consultation with private laboratory associations and legal experts, licencing guidelines for private laboratories could be amended to include reporting obligations. The updated requirements could be published and circulated to stakeholders, using national bulletins, newsletters and laboratory platforms. Countries can also develop a compliance monitoring system linked to DHIS2/IDSR, ideally featuring automated alerts and dashboards to make it easier to track and enforce adherence to reporting guidelines. In addition, private laboratories should ideally be offered training on the revised legal obligations and tools, via national and regional orientation sessions. To ensure compliance with the regulations, incentives related to legal, reputational and procurement considerations could be applied.

Key considerations for action:

- Enact regulations requiring private laboratories to report notifiable diseases within defined timeframes and integrate private facilities into electronic surveillance platforms.

- Provide regular training on reporting requirements and feedback on data quality and timeliness.

- Establish enforcement mechanisms, such as licence suspension for persistent non-reporting, and align reporting mandates with International Health Regulations and IDSR frameworks.

BEST PRACTICES

As a best practice, countries should legally mandate disease reporting from private laboratories by embedding obligations in national health legislation, public health acts, and facility licensing conditions. Key best practices within this include:

1. **Review and amend legal instruments.**
Conduct a review of existing public health laws, laboratory regulations, and licensing protocols to identify gaps in surveillance obligations for private diagnostic providers.

2. **Draft reporting clauses.** Develop legal clauses that specify**:**
- types of notifiable diseases to be reported (e.g., TB, HIV, AMR, Ebola, malaria, etc.),
- timelines for reporting (e.g., weekly, real-time for priority pathogens)
- the required data elements and formats
- penalties for non-compliance (e.g., license suspension, removal from national directories).

3. **Link to licensing and reimbursement.**

Make reporting a condition for:
- initial and renewed laboratory licenses
- access to public procurement, training programmes, or results-based financing
- eligibility for inclusion in MoU/PPP partnerships.

In South Africa, the National Health Act mandates electronic reporting of TB, COVID-19 and other notifiable conditions across the National Health Laboratory Service network of 233 laboratories across nine provinces.[23,24]

4. **Monitor and enforce compliance.**
Establish a national compliance dashboard or tracker linked to surveillance platforms. Use automated alerts to flag non-reporting laboratories and follow up with inspection teams or enforcement units.

In India, the National Tuberculosis Elimination Programme embedded TB case reporting into the Ni-kshay platform, making it mandatory for both public and private laboratories.[25] *Compliance was tied to accreditation, digital access, and reimbursement eligibility. Private laboratories that reported consistently*

received performance-based incentives. This approach led to a 45% increase in TB notifications from the private sector and significantly reduced diagnostic delays for vulnerable populations.

5. **Engage and sensitise.**
Conduct targeted advocacy sessions with private laboratory owners and legal officers to explain the public health rationale, benefits, and compliance pathways.

STEP 6:

DIGITALLY INTEGRATING LABORATORY INFORMATION SYSTEMS AND SURVEILLANCE REPORTING

AIM:

Create seamless, secure electronic links between private laboratories and national surveillance platforms to enable real-time reporting and data sharing.

WHY IT IS IMPORTANT:

Manual transmission of results is slow and error prone, and delays impede outbreak response and treatment. In contrast, linking LISs to national platforms removes the need for manual data entry and supports automation.

The effective integration of LISs into national health data platforms is a critical enabler of real-time disease surveillance, outbreak detection, and data-driven decision-making. While many public laboratories are already connected to platforms such as DHIS2, HMIS, or IDSR, private laboratories are often excluded, despite generating a substantial proportion of diagnostic data. This results in notable blind spots in disease trend monitoring, poor coordination during outbreaks, and underreporting of notifiable conditions, such as TB, HIV, AMR, and malaria.

Digital integration is a public health imperative as well as a technical exercise. By linking private LISs (or manual systems) with national databases, countries can close surveillance gaps, harmonise patient tracking, and accelerate treatment initiation. This step ensures that diagnostic insights from all sectors are captured in a timely and standardised manner.

KEY CONSIDERATIONS

A key consideration for this step is the need for private laboratories to have LISs capable of interfacing with national platforms, as a precursor to digitally integrating LISs and surveillance reporting. As part of digital integration, countries could initially map existing LISs in private laboratories and define minimum data standards for reporting, ensuring alignment with existing system architecture (e.g., DHIS2/IDSR). As a next step, LIS integration protocols (application programming interface [API] specifications) could be developed or adapted as needed to enable integration. These protocols could specify data formats, security protocols, and synchronisation intervals. Countries could consider offering training to private laboratory staff on digital reporting workflows. There is also an opportunity to encourage cross-sector learning, with public and private sector technical staff sharing best practices and expertise around the use of LISs.

To facilitate the integration process, countries could consider deploying reporting templates or LIS connectors. LIS connectors are software bridges or middleware components that allow an LIS to communicate and exchange data with other digital systems. As a result, LIS connectors are important to enable compatibility with national and local laboratory systems. A set of private laboratories can be selected to pilot data reporting, test integration, resolve issues, and collect feedback on the process for improvement. Once private LISs and surveillance reporting have been integrated with national systems, real-time data flow and performance should be monitored, ideally using dashboards to ensure timely and complete data submissions. Countries could also consider providing IT support and periodic retraining to respond to challenges and sustain engagement with the integration process.

Key considerations for action:

- Require private laboratories to implement an LIS capable of interfacing with national platforms such as DHIS2 or disease specific reporting systems.

- Develop interoperability standards and pilot electronic data exchange with a small cohort of private laboratories, gradually scaling up.

- Provide training on data standards, cybersecurity and patient confidentiality, and offer middleware solutions to low-resource laboratories.

BEST PRACTICES

There are several best practices for the digital integration of LISs and surveillance reporting between private and public laboratories. Countries should strive to connect all private laboratory data systems – whether electronic LISs or manual registers – to national disease surveillance platforms. When initiating the exercise, priority should be given to high-burden conditions and laboratories with diagnostic capacity in underserved or urban centres. Other best practices include:

1. **Enable API-based system linkage.**
   Use secure, open-source APIs to allow LIS data export from private laboratories into national platforms like DHIS2 or HMIS. Define data fields, validation rules, and reporting frequency in alignment with national surveillance requirements.

   In Uganda, the MoH implemented a nationwide LIS integration framework through its Central Public Health Laboratories, linking both public and private laboratories to the national DHIS2-based surveillance system. Private laboratories were mandated to report TB, HIV, and malaria data via electronic means. The result: a 60% increase in TB notifications from the private sector, faster patient follow-up, and enhanced outbreak preparedness across districts.

   Ethiopia's TB programme uses DHIS2 for case-based reporting, and the Ministry of Health is piloting digital reporting across 67 facilities.[26] The move to individual case-based reporting comes against a challenging backdrop: in 2020 an estimated 151,000 people developed TB in Ethiopia, but only 108,714 were notified.[26] Digital integration must also contend with limited connectivity – only around 39% of the population owns a mobile phone, 11% use smartphones and 21% have access to the internet.[26] Meanwhile, in Kenya, private laboratories have been integrated into the TIBU system for TB notification.[18]

2. **Create manual-to-digital bridges.**
   For private laboratories using paper-based systems, provide digital reporting templates (e.g., Excel, KoboToolbox) or develop mobile apps to facilitate secure submission of aggregated test results.

3. **Invest in digital literacy and infrastructure.**
Offer targeted training for private laboratory personnel on digital tools, data privacy, basic cybersecurity, and reporting protocols. Provide support for LIS installation or upgrades where feasible, especially in laboratories willing to align with public health programmes.

As an example, Ghana is developing a digital Health Facilities Regulatory Agency licensing and quality system to connect its more than 800 public clinical laboratories and emerging private sector.[27,28]

4. **Incentivise reporting compliance.**
Tie participation in data reporting to benefits such as inclusion in public referral networks, access to subsidised reagents, or priority accreditation support.

STEP 7:

CREATING INCENTIVE SCHEMES AND SHARED PROCUREMENT MODELS

AIM:

Sustain engagement by rewarding compliance and reducing the cost burden for private laboratories.

WHY IT IS IMPORTANT:

Regulations alone cannot sustain participation. Many private laboratories operate on slim margins and may be reluctant to undertake unfunded public health activities. As a result, offering incentives can motivate participation and shared procurement can reduce costs for private laboratories.

Despite their large footprint, many private laboratories remain disconnected from national laboratory systems due to a lack of motivation or perceived benefit from integration. To overcome this, countries must design incentive structures that reward participation, data sharing, quality compliance, and alignment with national diagnostic priorities. Incentives not only accelerate integration but also demonstrate mutual value, turning regulation into collaboration.

Moreover, the high cost of diagnostics, reagents, and equipment is a major barrier for small- and medium-sized private laboratories, particularly in underserved areas. By allowing private providers to benefit from shared procurement models, governments can create win-win mechanisms that improve affordability, standardise commodity access, and expand testing capacity.

This step therefore focuses on making public-private collaboration financially and operationally attractive and encouraging private sector alignment with national strategies while preserving sustainability.

KEY CONSIDERATIONS

As part of creating incentive schemes and shared procurement models for private laboratories, countries could consider designing a national tiered incentive framework to define benefits based on data reporting, EQA and accreditation level. Stakeholders could be engaged on the design of this framework to ensure buy-in and align incentives with laboratory realities. Countries are encouraged to publish and clearly communicate incentive eligibility criteria through national bulletins and laboratory portals. Countries could also consider establishing a joint procurement access policy, to define the conditions under which private laboratories can join pooled procurement. Additionally, a monitoring and evaluation system could be established to track laboratory compliance and progress towards reward thresholds. Countries are encouraged to consider piloting the incentive model with selected private laboratories, starting with TB/HIV-focused laboratories in high-burden areas. Findings from the pilot can be used to refine the model, ahead of scaling up the incentive framework nationally.

Key considerations for action:

- Offer financial incentives via digital payments for timely reporting, EQA participation, case detection, and use of priority tests.
- Create pooled procurement mechanisms to allow private laboratories to access reagents and equipment at bulk purchase prices and reduce stockouts.
- Provide non-financial incentives such as public recognition, certificates of excellence, access to continuing education and preferential access to new diagnostics.

BEST PRACTICES

As best practice, countries should design and implement a tiered incentive framework linked to private laboratory performance in reporting, quality, and surveillance. Private laboratories should also be integrated into pooled procurement schemes for reagents and diagnostics.

Key best practices include:

1. **Develop a tiered incentive system.**
   In collaboration with the Ministry of Finance and procurement agencies, create a framework with multiple entry points, e.g.,:
   - **Tier 1:** Laboratories enrolled in EQA and reporting to DHIS2 receive free training and national directory listing.
   - **Tier 2:** Laboratories meeting >80% data compliance and passing EQA become eligible for subsidised reagents or joint procurement access.
   - **Tier 3:** ISO-accredited laboratories participating in PPPs qualify for national contracts and results-based financing. Also known as performance-based financing, this mechanism provides payments or incentives contingent on the achievement of specific, measurable results. *Results-based financing has been used in Nigeria's broader health sector to improve service coverage and quality, particularly in HIV, TB, maternal health, and now increasingly in AMR and other diagnostic services.*

2. **Enable shared procurement access.**
   Allow qualified private laboratories to access bulk reagent procurement contracts negotiated by the government. This improves affordability and quality assurance across the diagnostic ecosystem.

3. **Offer tax and regulatory incentives.**
   Explore targeted tax relief (e.g., on diagnostic commodities), fast-tracked registration, digital payments, or subsidised equipment leasing for participating private laboratories.

   Kenya's PPM plan uses digital payments to provide incentives and enablers to both providers and patients.[18] These payments help offset the real costs faced by private facilities: in some Kenyan private clinics, a GeneXpert test may cost up to KSh 9000 (about US$60), an acid fast bacillus smear around KSh 1100 and a chest X-ray about KSh 2200.[18]

4. **Communicate clearly.**
   Publish eligibility criteria, timelines, and procedures for laboratories to join the incentive programme through laboratory associations, MoH portals, and EQA newsletters.

STEP 8:

MONITORING PROGRESS AND INSTITUTIONALISING FEEDBACK LOOPS

AIM:

Track the outcomes of integrating private sector laboratories in national laboratory networks, identify bottlenecks, and continuously improve the collaboration.

WHY IT IS IMPORTANT:

Integration is a journey, not a one-off event. Continuous monitoring ensures laboratories maintain standards, report consistently, and receive the support they need. Feedback loops also reinforce trust: when laboratories see their data driving public health action, they remain engaged.

The integration of private medical laboratories into national laboratory networks is a dynamic and iterative process. Without structured mechanisms to track progress and generate timely feedback, implementation may stall, misalign with public health priorities, or fail to sustain long-term collaboration. Effective monitoring ensures accountability, and allows for course correction, policy refinement, and adaptive learning across stakeholders.

Feedback loops can be created through joint performance reviews and the use of dashboards, which display key metrics related to the integration of private laboratories into national laboratory networks. Efforts to institutionalise these processes can strengthen transparency, nurture trust, and promote a culture of continuous improvement. It also provides an opportunity for government and private sector actors to co-own the integration journey, ensuring that successes are celebrated and gaps are collectively addressed.

KEY CONSIDERATIONS

Ahead of monitoring and evaluation, countries could define core indicators for PPP integration, considering metrics such as EQA participation, data reporting, and compliance with MoUs. Countries can consider designing a national integration performance dashboard, including interactive visualisations for tracking laboratory engagement. A private laboratory integration scorecard is also recommended to enable the annual evaluation of laboratories based on quality, reporting, and collaboration. Quarterly PPP review meetings can further facilitate joint progress reviews with public and private laboratories. Dashboard updates could be disseminated to stakeholders on a regular basis, to ensure visibility and accountability during the integration process. Throughout, it is important to collect feedback from private laboratories on the integration process, which can be obtained through surveys and interviews. The integration approach could then be adjusted based on feedback and performance data, with lessons incorporated into planning and SOP revisions. Additionally, countries can consider publishing an annual integration progress report, which summarises achievements, challenges, and next steps.

Key considerations for action

- Define indicators for licensing, accreditation, reporting timeliness, data quality, EQA participation, and case detection.
- Conduct regular supervision visits using standardised checklists – such as the Ugandan quality management support supervision checklist (Annex 2) – and follow up on corrective actions.
- Analyse performance data, share tailored feedback with private laboratories, and adjust support and incentives accordingly.
- Institutionalise regular review meetings between ministries and private sector representatives to refine strategies.

BEST PRACTICES

Establishing regular monitoring and feedback mechanisms is a key best practice for the effective integration of private and public laboratories. These monitoring and feedback mechanisms should include quarterly review meetings, integration dashboards, and annual performance scorecards to track compliance, highlight achievements, and flag challenges.

Key best practices include:

1. **Design a private laboratory integration dashboard.**
   Develop a visual dashboard to track the real-time progress of private laboratories on core integration metrics such as:
   - EQA participation and performance
   - surveillance reporting compliance
   - LIS integration status
   - participation in national meetings/TWGs
   - number of signed MoUs and accreditation milestones.

   The dashboard should be hosted by the MoH and updated monthly with inputs from EQA coordinators, surveillance teams, and PPP focal points.
   In Kenya, the MoH institutionalised quarterly joint PPP review sessions under the National Laboratory Technical Working Group. Using a national dashboard, stakeholders tracked private laboratory participation in EQA, reporting, and accreditation. Performance was reviewed collaboratively, and underperforming laboratories were offered mentorship support. Within two years, this approach resulted in a 25% increase in EQA compliance among private laboratories and improved public-private transparency.

2. **Convene quarterly joint review meetings.**
   Bring together key actors – MoH, national public health laboratories, private laboratory representatives, and development partners – to review dashboard findings. These sessions should be used to share lessons and innovations, validate scorecard data, propose new SOPs or revisions, and resolve bottlenecks in real time.

3. **Develop and publish an annual scorecard.**
   Create a nationally endorsed scorecard to rank private laboratory performance in integration. This tool can serve both as a recognition mechanism and as a benchmark for national programme planning.

4. **Institutionalise feedback mechanisms.**
   Allow private laboratories to provide structured feedback on their integration experience via digital forms, surveys, or live feedback during review meetings. Analyse this feedback to adjust strategies and policies.

In Uganda, the Allied Health Professionals Council requires private laboratories to submit applications and supporting documents; district focal persons then inspect facilities using a checklist and share signed reports for licensing.[29] *Regular oversight has contributed to Uganda having 73 internationally accredited human health laboratories across the public and private sectors as of late 2023.*[30]

5. **Tie monitoring to incentives and regulation.**
   Use performance findings to inform eligibility for incentives (e.g., pooled procurement) or regulatory actions (e.g., EQA support withdrawal for non-compliance).

   Tanzania requires annual re-registration and verification of corrective actions.[31] By tracking accreditation status, staffing levels and quality indicators, ministries can tailor support and incentives and sustain improvements. Continuous monitoring is important: a star rating assessment of 6663 primary healthcare facilities in Tanzania found that only 27% met staffing requirements and that private/urban facilities scored significantly higher on quality compliance than public/rural ones.[32]

CROSS-CUTTING CONSIDERATIONS

1. **Strengthen legal and policy frameworks.** National laws should explicitly require private laboratories to obtain licences, meet quality standards, and report notifiable diseases.

2. **Invest in workforce and capacity building.** Extend national and regional training programmes (e.g., SLMTA/SLIPTA) to private laboratories to address staffing shortages and skill gaps.

3. **Promote harmonisation and collaboration.** Align disease-specific programmes and encourage information sharing via networks such as the National Public Health Institutes and LabCoP.

4. **Ensure sustainable financing.** Earmark a portion of licence fees and donor funding for oversight, training, and digital infrastructure.

5. **Address data security and privacy.** Establish clear policies on data ownership and confidentiality, and implement technical safeguards such as encryption and audit logs.

6. **Embrace innovation and adaptation.** Encourage local innovation and partnerships with academia and the private sector to develop home-grown digital solutions.

CONCLUSIONS

Integrating private medical laboratories into national laboratory networks is essential for a strong and responsive diagnostic system. Through effectively connecting private and public laboratories, countries can transform fragmented systems into cohesive, resilient networks. This recipe provides countries with key considerations, best practices, and tools to sustainably integrate private sector laboratories into national laboratory networks. These efforts are vital to improve diagnostic equity and capacity across LMICs, and strengthen pandemic preparedness and health security.

REFERENCES

1. Goodman C, Witter S, Hellowell M, et al. Approaches, enablers and barriers to govern the private sector in health in low- and middle-income countries: a scoping review. BMJ Global Health 2024; 8: e015771. DOI: 10.1136/bmjgh-2024-015771.

2. Yadav H, Shah D, Sayed S, et al. Availability of essential diagnostics in ten low-income and middle-income countries: results from national health facility surveys. The Lancet Global Health 2021; 9: e1553-e1560. DOI: https://doi.org/10.1016/S2214-109X(21)00442-3.

3. Sayed S, Cherniak W, Lawler M, et al. Improving pathology and laboratory medicine in low-income and middle-income countries: roadmap to solutions. The Lancet 2018; 391: 1939-1952. DOI: https://doi.org/10.1016/S0140-6736(18)30459-8.

4. Uganda Ministry of Health – Central Public Health Laboratories. Laboratory Results Dispatch System (LabRDS) and Laboratory Information System (A-LIS) implementation overview, https://aslm.org/aslmacademy (2024, accessed 15 June 2026).

5. African Society for Laboratory Medicine. LabCoP Cookbook of best practices: Recipe #9: Electronic return and notification of test results, https://aslm.org/resource/labcop-cookbook-recipe-9-electronic-return-and-notification-of-test-results/ (accessed 15 June 2026).

6. World Health Organization. Public–private mix for TB prevention and care: a roadmap, https://www.who.int/docs/default-source/documents/tuberculosis/ppmroadmap.pdf (2018, accessed 15 June 2026).

7. World Health Organization. International Health Regulations, https://www.who.int/health-topics/international-health-regulations#tab=tab_1 (accessed 15 June 2026).

8. World Health Organization. Universal health coverage (UHC), https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc) (accessed 15 June 2026).

9. National Tuberculosis LaLDPN-P. Kenya TB Annual Report 2023, https://nltp.co.ke/wp-content/uploads/2025/03/2023-Annual-Report.pdf (2023, accessed 15 June 2026).

10. African Society for Laboratory Medicine. Laboratory Mapping Program (LabMaP), https://aslm.org/our-expertise/laboratory-mapping-program/ (accessed 15 June 2026).

11. World Health Organization Regional Office for Africa. Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist, https://aslm.org/wp-content/uploads/2019/12/SLIPTA-Checklist-V3-22-Dec-2023.pdf?x79169 (2023, accessed 15 June 2026).

12. World Health Organization. Service availability and readiness assessment (SARA), https://www.who.int/data/data-collection-tools/service-availability-and-readiness-assessment-(sara) (accessed 15 June 2026).

13. Medical Laboratory Science Council of Nigeria (MLSCN). Publications, https://www.mlscn-as.org.ng/publications.html (accessed 15 June 2026).

14. Medical Laboratory Science Council of Nigeria (MLSCN). Laboratory Licensing Requirements, https://web.mlscn.gov.ng/wp-content/uploads/2023/03/mlscn-laboratory-guidelines.pdf (accessed 15 June 2026).

15. Bello S, Adebowale AS, Dairo MD, et al. COVID-19 TESTING PERFORMANCE AND STRATEGIES FOR RAPID SCALE UP OF LABORATORY CAPACITY IN A PUBLIC HEALTH EMERGENCY IN A RESOURCE-CONSTRAINED SETTING: THE SARS-COV-2 NIGERIA RESPONSE EXPERIENCEJ. Ann Ib Postgrad Med 2025; 23: 69-79. 2025/08/25.

16. Al-Mustapha AI, Tijani AA, Oyewo M, et al. Nigeria's race to zero COVID-19 cases: True disease burden or testing failure? J Glob Health 2021; 11: 03094. 2021/08/20. DOI: 10.7189/jogh.11.03094.

17. The Global Fund. Private Sector Engagement in Tuberculosis Care. 10 November 2025 2025.

18. Kenya Ministry of Health. Public Private Mix (PPM) Action Plan 2021–2023, https://chskenya.org/wp-content/uploads/2022/04/TB-PPM-Action-Plan-2021-2023.pdf (accessed 15 June 2026).

19. Torokaa PR, Massambu C, Lusekelo J, et al. Strengthening laboratory management towards accreditation in Tanzania: The 13 years of remarkable revolutions in laboratory quality management system. PLOS ONE 2026; 21: e0320823. DOI: 10.1371/journal.pone.0320823.

20. ISO. ISO 15189:2022, https://www.iso.org/standard/76677.html (2022, 15 June 2026).

21. African Society for Laboratory Medicine. Guidance for Establishing a National Laboratory Quality Framework https://aslm.org/resource/guidance-for-establishing-a-national-laboratory-quality-framework-2/ (2026, 15 June 2026).

22. South African National Accreditation System (SANAS). Overview, https://www.sanas.co.za/pages/index.aspx?page=latest-overview (accessed 15 June 2026).

23. Government of South Africa. National Health Act: Regulations: Surveilance and control of notifiable medical conditions, https://www.gov.za/documents/notices/national-health-act-regulations-surveilance-and-control-notifiable-medical (2025, accessed 15 June 2026).

24. Department of Health Republic of South Africa. Annual Performance Plan 2024-2025, https://www.health.gov.za/wp-content/uploads/2024/04/Health-Annual-Performance-Plan-2024-02-04-2024-Final.pdf (2024, 15 June 2026).

25. Ministry of Health & Family Welfare. Ni-kshay, https://www.nikshay.in/Home/AboutUs (accessed 15 June 2026).

26. Stop TB Partnership. Digital TB Surveillance System Assessment Report: Ethiopia, https://tbassessment.stoptb.org/assets/docs/Digital%20TB%20Surveillance%20System%20Assessment%20All%20Country%20Reports/Ethiopia%20Digital%20TB%20Surveillance%20System%20Assessment%20Report.pdf (2022, accessed 15 June 2026).

27. Health Facilities Regulatory Agency (HeFRA). License Requirement, https://hefra.gov.gh/license-requirement/ (accessed 15 June 2026).

28. Kploanyi EE, Kenu J, Atsu BK, et al. An assessment of the laboratory network in Ghana: A national-level ATLAS survey (2019-2020). Afr J Lab Med 2023; 12: 1844. 2023/03/07. DOI: 10.4102/ajlm.v12i1.1844.

29. The Allied Health Professionals Council. Requirements, https://ahpc.ug/page/requirements (2025, accessed 15 June 2026).

30. National Health Laboratory and Diagnostic Services. Uganda emerged Second on Africa continent with most accredited Laboratories, https://www.cphl.go.ug/web/uganda-emerged-second-africa-continent-most-accredited-laboratories (2023, accessed 10 November 2025).

31. Blackhall Publishing. Law of Tanzania, https://tanzanialaws.com/sub-p/588-private-health-laboratories-regulation-act (accessed 15 June 2026).

32. Kinyenje E, Ngowi RR, Msigwa YS, et al. Status of countrywide laboratory services quality and capacity in primary healthcare facilities in Tanzania: Findings from Star Rating Assessment. PLOS Glob Public Health 2023; 3: e0001489. 2023/10/18. DOI: 10.1371/journal.pgph.0001489.

ANNEX:

1. MEMORANDUM OF UNDERSTANDING TEMPLATE, NIGERIA

MEMORANDUM OF UNDERSTANDING (MoU)

BETWEEN
GUILD OF MEDICAL LABORATORY DIRECTORS (GMLD) ("Principal")
AND
MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA (MLSCN) ("Partner")

Purpose

This MoU outlines the collaborative framework between GMLD and MLSCN for the delivery of quality medical laboratory services across Nigeria. The agreement sets out the principles, responsibilities, and commitments of both parties to strengthen laboratory systems, ensure regulatory compliance, and enhance service quality in line with international standards such as ISO 15189.

Parties

1. **GMLD:** The Guild of Medical Laboratory Directors, with its registered office at [Full Address], hereinafter referred to as "the Principal," which includes its successors-in-title and assigns.

2. **MLSCN:** The Medical Laboratory Science Council of Nigeria, with its headquarters at [Full Address], hereinafter referred to as "the Partner," which includes its successors-in-title and assigns.

Background

1. GMLD is committed to advancing the professional, operational, and business interests of private sector medical laboratories in Nigeria.
2. MLSCN, as the regulatory authority, is committed to ensuring the quality, safety, and ethical standards of all medical laboratories operating within Nigeria.
3. Both parties recognize the importance of collaboration in strengthening the quality of medical laboratory services and advancing public health outcomes.

Joint Responsibilities

The Parties agree to collaborate on the following:
Promote adherence to ISO 15189:2022 standards and other applicable regulatory frameworks.
Support continuous professional development (CPD) initiatives for medical laboratory professionals.

Facilitate quality audits, proficiency testing, and external quality assessment (EQA) programs.
Share relevant data and insights to improve quality service delivery and public health reporting.

Collaborate in advocacy, policy engagement, and awareness campaigns on the importance of quality laboratory services.

Encourage innovation, research, and adoption of digital technologies for enhanced quality monitoring and service delivery.

GMLD Responsibilities

Provide logistical and technical support for joint quality improvement initiatives.
Encourage members to participate actively in EQA schemes and CPD programs.

MLSCN Responsibilities

Provide regulatory oversight, technical guidelines, and support for quality service delivery.
Facilitate accreditation and licensing processes for member laboratories in compliance with applicable standards.
Deliver targeted training, mentorship, and technical assistance for laboratory quality improvement.

Duration

This MoU shall take effect from the date of signing by both parties and remain valid for an initial period of [X YEARS], renewable by mutual agreement. Either party may terminate the agreement with [X DAYS/MONTHS] written notice.

Dispute Resolution

In the event of disputes, the parties agree to first seek resolution through constructive dialogue and mediation. If unresolved, disputes shall be referred to arbitration under Nigerian law. Court litigation shall be a last resort.

Review and Amendment

This MoU may be reviewed and amended at any time by mutual written agreement of both parties.

Signatures

This MoU is signed in good faith and signifies the full understanding and agreement of both parties.

For the GMLD:

Name: _____

Title: _____

Signature: _____

Date: _____

For the MLSCN:

Name: _____

Title: _____

Signature: _____

Date: _____

ANNEX:

2. EXAMPLE LABORATORY QUALITY MANAGEMENT SUPPORT SUPERVISION CHECKLIST

SECTION A: LABORATORY IDENTIFICATION DATA

1. District: .....

2. Name of Health Facility: .....

3. Level of Facility (Tick the applicable option)

☐ HC II ☐ HC III ☐ HC IV ☐ • General Hospital ☐ Regional Referral Hosp. ☐ National Referral Hospital

4. Ownership of Health Facility (Tick the applicable option)

☐ Government ☐ Private for profit ☐ Private not for profit ☐ Others (Specify): .....

SECTION B: FACILITY IN CHARGE CONTACT DETAILS

5(a). Name of Health Facility In Charge .....

5(b). Tel. No. of Health Facility In Charge .....

5(c). Email address of Health Facility In Charge: .....

SECTION C: LABORATORY IN CHARGE CONTACT DETAILS

6(a). Name of Laboratory In Charge .....

6(b). Tel. No. of Laboratory In Charge .....

6(c). Email address of Laboratory In Charge .....

SECTION D: LABORATORY LEGAL IDENTITY

7. Legal entity: Does the laboratory have Allied Health Professional Council (AHPC) documentation stating its legal identity? ☐ Yes ☐ No

8(a). If 7 is yes, state the AHPC registration certificate number .....

8(b). If 7 is yes, is there a current AHPC Annual Practicing License for the Laboratory?

☐ Yes ☐ No

SECTION E: NUMBER OF LABORATORY PERSONNEL

9a.	How many permanent Lab. Assistants including those seconded by IPs does the laboratory have?	.....
9b.	How many permanent Lab. Technicians including those seconded by IPs does the laboratory have?	.....
9c.	How many permanent Lab. Technologists including those seconded by IPs does the laboratory have?	.....
10	Total number of technical staff the laboratory has	.....

SECTION F: KEY LABORATORY PERSONNEL

Note:
For questions 11-13, there must be documented evidence to show that the key personnel have been appointed before you tick yes

11. Does the laboratory have an appointed Laboratory Director? ☐ Yes ☐ No

12. Does the laboratory have an appointed Laboratory Quality Officer? ☐ Yes ☐ No

13. Does the laboratory have an appointed Laboratory Manager/Laboratory In Charge?

☐ Yes ☐ No

14. Does the laboratory have an appointed Laboratory Biosafety Officer? ☐ Yes ☐ No

SECTION G: MANDATORY MANAGERIAL DOCUMENTATION

15(a). Does the laboratory have a documented Quality Policy Statement? ☐ Yes ☐ No

15(b). Does the laboratory have a Laboratory Quality Manual? ☐ Yes ☐ No

16. Does the laboratory have the following mandatory quality management system standard operating procedures?

ISO 15189:2012 required SOPs		Does the laboratory have this SOP?	ISO 15189:2012 Clause
16.a	Document control	☐ Yes ☐ No	
16.b	Establishment of services agreements	☐ Yes ☐ No	
16.c	Selection and evaluation referral laboratories and consultants SOP	☐ Yes ☐ No	
16.d	External services and supplies	☐ Yes ☐ No	
16.e	Resolution of complaints	☐ Yes ☐ No	
16.f	Identification and control of NCs	☐ Yes ☐ No	
16.g	Corrective action	☐ Yes ☐ No	
16.h	Preventive action	☐ Yes ☐ No	
16.i	Control of records	☐ Yes ☐ No	
16.j	Internal audit	☐ Yes ☐ No	
16.k	Personnel management	☐ Yes ☐ No	
16.i	Selection, purchase & management of equipment	☐ Yes ☐ No	
16.m	Calibration of equipment	☐ Yes ☐ No	
16.n	Equipment preventive maintenance	☐ Yes ☐ No	
16.o	Reagents and consumables	☐ Yes ☐ No	

16.p	Pre-examination	☐ Yes ☐ No
16.q	Verbal requests	☐ Yes ☐ No
16.r	Primary sample collection and handling	☐ Yes ☐ No
16.s	Sample transportation	☐ Yes ☐ No
16.t	Sample acceptance and rejection criteria	☐ Yes ☐ No
16.u	Verification and examination procedures	☐ Yes ☐ No
16.v	Validation of examination procedures	☐ Yes ☐ No
16.w	Inter-laboratory comparison	☐ Yes ☐ No
16.x	Results review	☐ Yes ☐ No
16.z	Storage, retention and disposal of clinical samples	☐ Yes ☐ No
16.z.a	Release of results	☐ Yes ☐ No
16.z.b	Automated selection and reporting of results	☐ Yes ☐ No
16.z.c	Information systems management	☐ Yes ☐ No

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