



# **Advancing Laboratory Systems To Ensure Equitable Access To Healthcare : A Global Perspective**



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# ADVANCING LABORATORY SYSTEMS TO ENSURE EQUITABLE ACCESS TO HEALTHCARE : A GLOBAL PERSPECTIVE

Health laboratory systems are the backbone of equitable healthcare, supporting disease prevention, diagnosis, and treatment. By advancing laboratory systems globally, we can ensure that every individual, regardless of their background or location, has access to safe, accurate, and timely diagnostic services.

## 1. Introduction

Robust laboratory system is of utmost importance in disease control and prevention, providing vital support for diagnosis, treatment management, screening, and surveillance. Both clinical and public health laboratories play key roles in these efforts. Clinical laboratories focus on individual patient care, while public health laboratories primarily contribute to disease control and prevention. The data generated by these laboratories are essential in clinical and public health settings, enabling effective case management, surveillance, and early detection of public health events. In the face of outbreaks and potential national security threats posed by known and emerging diseases, laboratories have become even more crucial. **Accurate and reliable laboratory services are integral to strong and effective health systems.**

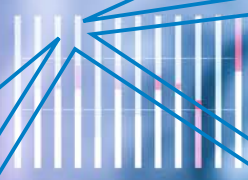
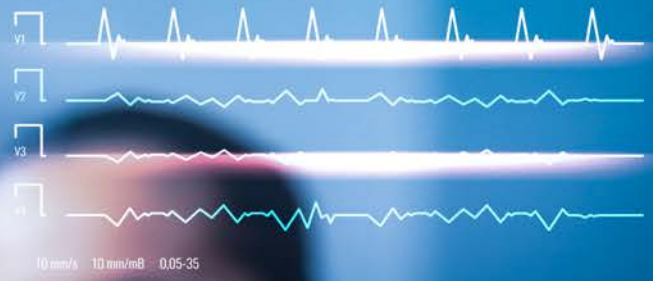
Over the years, international organizations and stakeholders have recognized the crucial role of laboratories in disease diagnosis and care, calling for the integration of laboratory services into broader health systems. However, significant challenges persist, including limited laboratory capacity, inadequate funding, fragmented services, and barriers to access.

This report presents a comprehensive overview of global efforts to strengthen laboratory systems, highlighting key initiatives, strategic frameworks, and collaborations to address these challenges. Despite over 15 years of global initiatives to improve diagnostic capabilities, the progress has been slow. The report underscores the need for sustained commitment and innovative approaches to ensure universal access to quality laboratory services by examining the advancements made in essential diagnostics, capacity building, and pandemic preparedness.

## 2. Enhancing Laboratory Systems: The Maputo Declaration's Call for Quality-Assured Services and Integrated Healthcare Strengthening (2008)<sup>1</sup>

In 2008, recognizing the critical role of laboratories, World Health Organization (WHO) leaders emphasized on the importance of quality-assured laboratory services in resource-limited settings, and urged the member states to integrate them into the broader health systems was essential for overall healthcare strengthening. As such, the Maputo Declaration was formulated during a Consensus Meeting held in Maputo, Mozambique in January 2008, with an aim to address the challenges in laboratory systems that hindered the services for neglected tropical diseases, including, tuberculosis, malaria, and HIV diagnosis and care.

The declaration acknowledged the significant burden of these diseases globally, with millions of individuals affected and inadequate detection rates. Insufficient laboratory capacity was identified as a significant barrier to implementing and sustaining prevention, treatment, and care programs. Other identified challenges were lack of leadership, untrained workforce, poor infrastructure, and inadequate quality assurance, were identified in resource-limited settings. To combat these issues, increased funding had been secured from donors, emphasizing the integration of laboratory support for the three diseases. National governments of member states were urged to prioritize laboratory systems by developing policies and strategic plans supported by dedicated departments within Ministries of Health. Collaboration between governments, donors, and partners was stressed, focusing on national ownership and public-private partnerships. Attention was also drawn to the need for comprehensive laboratory human resources planning and financing and the development of new diagnostic tools suitable for resource-limited settings. The Maputo Declaration called for an urgent action to strengthen laboratory systems, ultimately contributing to a unified and integrated national laboratory network.



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### 3. Strategic Approaches for Strengthening Health Laboratories: The Asia Pacific Perspective (2010)<sup>2</sup>

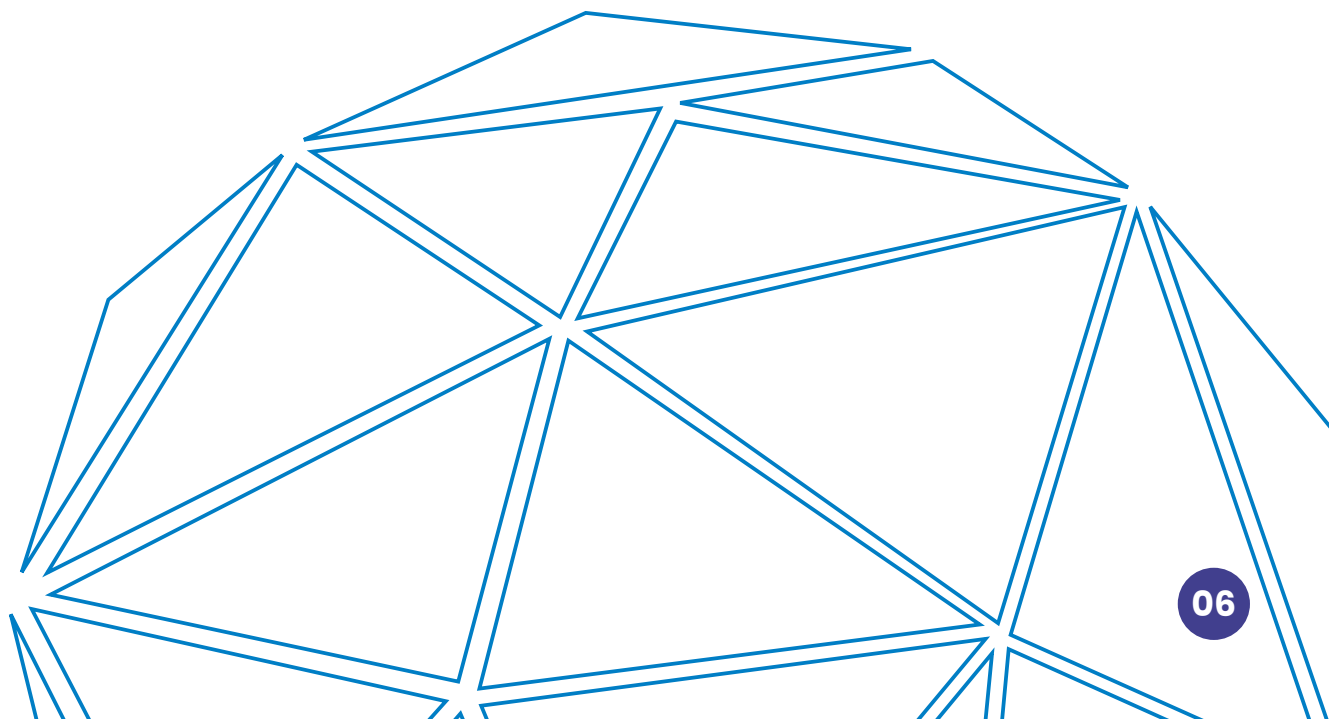
In the Asia Pacific Region, although efforts have been made to improve health laboratory services, the focus has predominantly been on specific disease control programs, leading to fragmented laboratory services and inadequate allocation of resources to other areas of the laboratory system. To mitigate these challenges, the Asia Pacific Strategy for Strengthening Health Laboratory Services (2010–2015) was launched to assist Member States in providing comprehensive laboratory services to contribute to better health outcomes.

Recognizing the need for tailored approaches, the strategy suggests adapting the framework to national or regional contexts and integrating it with existing health policies, strategies, and resources. It advocates for establishing a sustainable national framework, including a national laboratory policy, regulatory mechanisms, and a laboratory plan, with designated focal points and oversight mechanisms to deliver safe and quality laboratory services. The strategy also underscores the significance of adequate resources and appropriate financing mechanisms to promote the rational use of services and proposes cost-effectiveness tools and prepaid pooled funding mechanisms. It highlights the need of capacity building, including designing a tiered laboratory network with suitable infrastructure, human resources, procurement, supply management, referral networks, and information systems. The strategy promotes quality, biosafety, occupational health, rational use of laboratory services, and operational research for appropriate technology utilization. In addition, the plan provides examples of best practices and highlights the role of WHO in supporting Member States in implementing each strategic element.

## 4. Empowering Laboratories for Better Health Outcomes: The Eastern Mediterranean Approach (2016)<sup>3</sup>

The strategic framework for strengthening health laboratory services in the WHO Eastern Mediterranean Region (2016–2020) aims to address the challenges faced by laboratory systems in the region. Despite the progress made in disease-specific programs, there are significant issues related to regulatory frameworks, funding, access, quality, equipment, and workforce competence. Laboratories often receive low priority and recognition within national healthcare systems. As such, the framework seeks to improve the population's health status by strengthening sustainable national health laboratory systems. **It guides priority setting, coordination among stakeholders, resource mobilization, and advocacy for ownership and support within ministries of health.**

The vision is to establish comprehensive, coordinated, integrated, and sustainable health laboratory services that provide safe, accurate, and timely test results for clinical and public health purposes. **The framework outlines six strategic goals, including strengthening leadership and governance, improving organization and management towards quality, ensuring competent human resources, promoting safe environments, enhancing referral networking and coordination, and encouraging rational and evidence-based use of laboratory services.** It includes SMART goals and associated activities for each goal. Implementation of the framework is crucial for improving the quality and safety of health laboratory services and fulfilling obligations under the International Health Regulations (2005).







## 5. Advancing Universal Health Coverage: The Model List of Essential In Vitro Diagnostics (2018)<sup>4</sup>

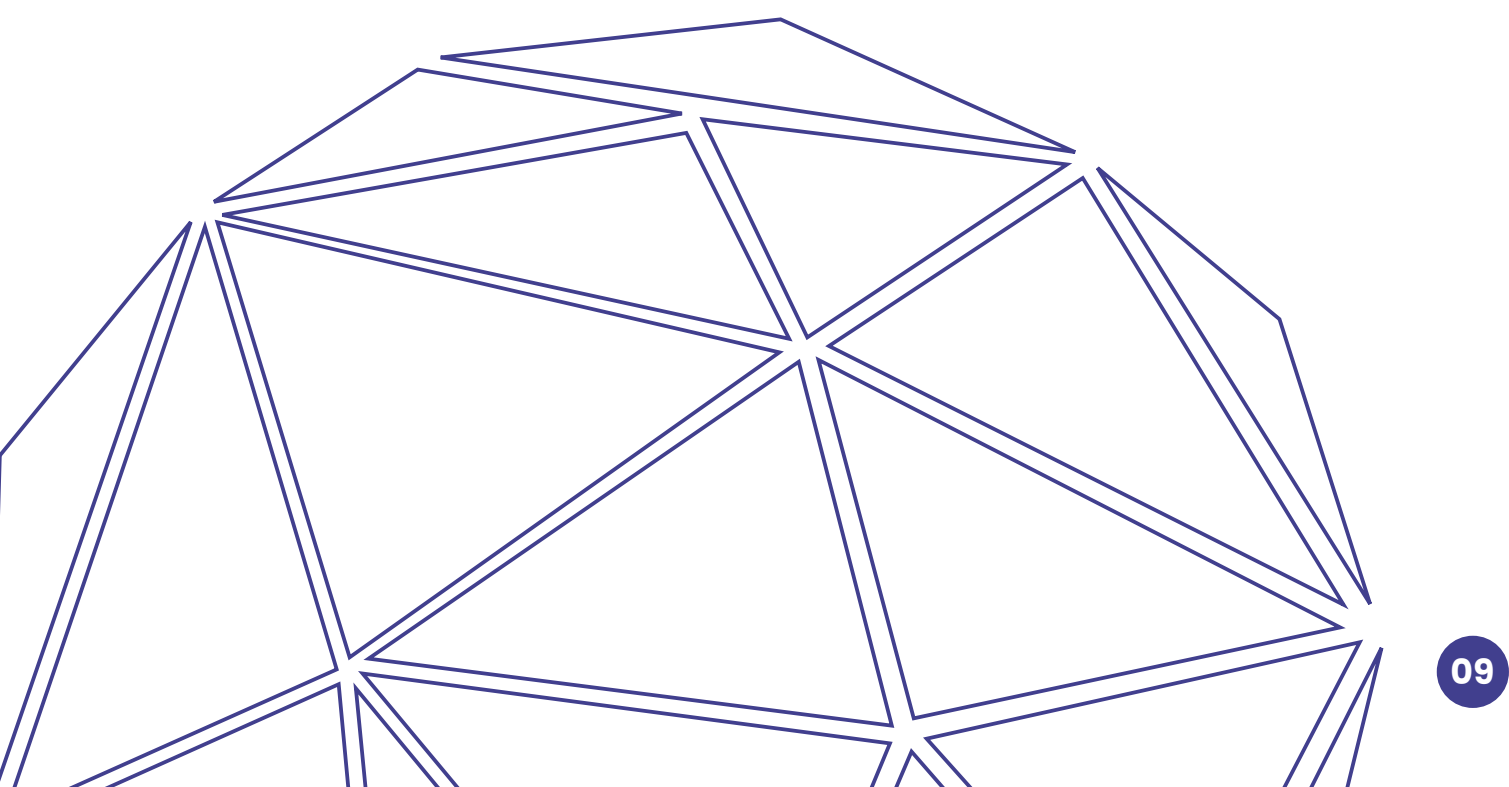
In 2018, the WHO published the Model List of Essential In Vitro Diagnostics (EDL). The EDL complements the WHO Model List of Essential Medicines (EML) and aims to guide countries in selecting and implementing necessary diagnostic tests based on their needs and priorities. It serves as a reference for ministries of health, program managers, laboratory managers, procurement officers, and reimbursement systems in developing and updating national lists of essential diagnostics.

Additionally, it informs United Nations agencies, non-governmental organizations, and the private sector on global health priorities and the necessary diagnostics. It is important to note that the EDL alone cannot improve access to diagnostics without a well-functioning laboratory system, including infrastructure, human resources, and quality assurance systems. The EDL includes general laboratory tests for routine care and detecting various diseases and difficulties specific to crucial disease areas such as HIV, TB, malaria, HBV/HCV, HPV, and syphilis. The list does not specify brands but describes tests based on their biological targets. It provides information on test purpose, assay format, specimen type, recommended facility level, and links to WHO guidance or prequalified/endorsed products. The EDL is organized into two tiers based on healthcare facility levels: In Vitro Diagnostics (IVD) for primary healthcare and IVDs for healthcare facilities with clinical laboratories.

## 6. Advancing Laboratory Medicine in Low-Income and Middle-Income Countries: Challenges, Progress, and the Way Forward (2018)<sup>5</sup>

The Lancet published a series in 2018 that analysed laboratory medicine challenges in low- and middle-income countries (LMICs). The access to quality laboratory diagnosis in LMICs poses challenges, leading to delayed and inaccurate diagnosis and ineffective treatment. The Lancet Series on Pathology and laboratory medicine (PALM) in LMICs addresses these challenges, including the lack of infrastructure, supplies, equipment, skilled personnel, and quality management systems. Global investments, advocacy, laboratory innovation, and shared commitment have contributed to significant progress in PALM. Programs such as Strengthening Laboratory Management Toward Accreditation (SLMTA) and Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) have improved the quality of laboratory diagnostic findings.

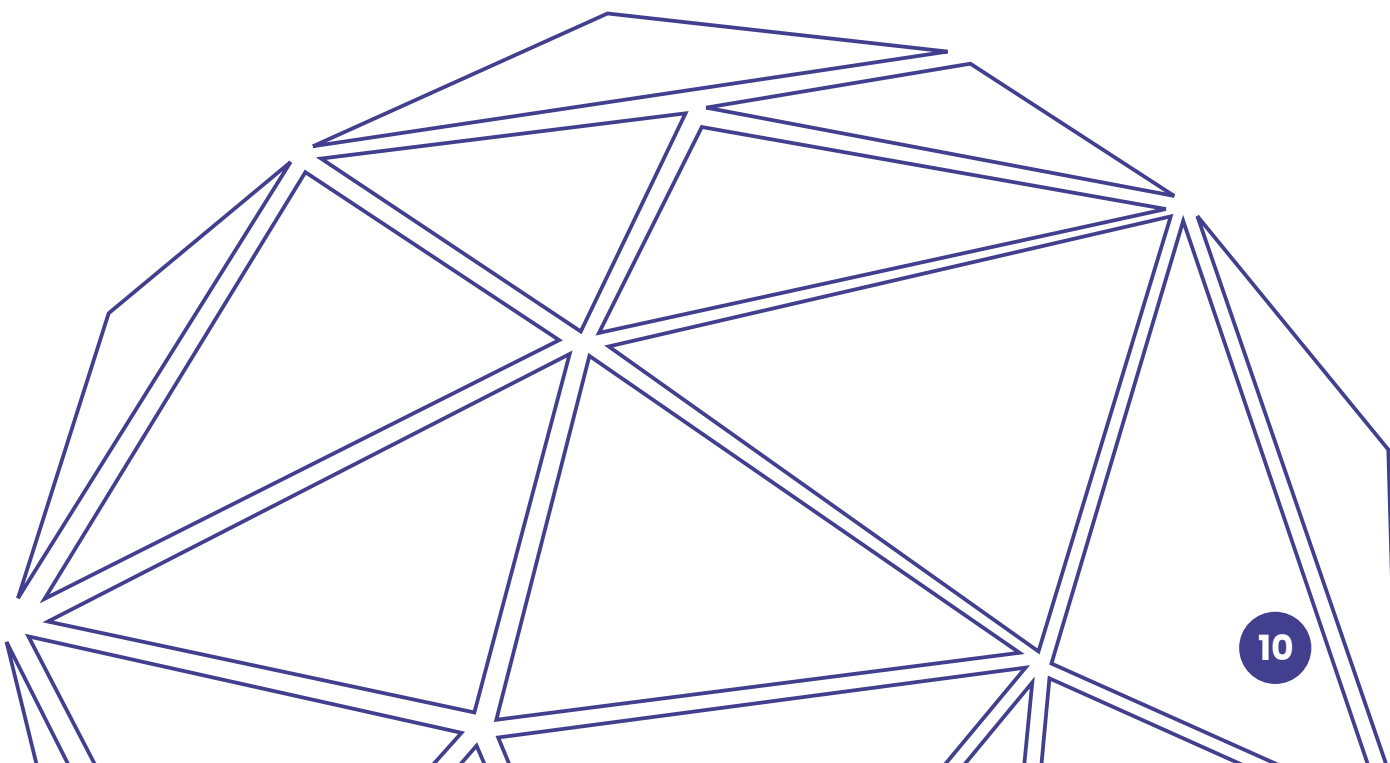
**Continued support and scaling up for such programs are crucial, along with investment in workforce development, infrastructure improvement, and innovation.** Integration of point-of-care diagnostics, strengthening laboratory-clinician interface, and regional coordination are essential for sustained progress in laboratory medicine and achieving universal health coverage in LMICs.



## 7. Unlocking Global Access to Essential Diagnostics: Overcoming Barriers and Embracing Innovation (2021)<sup>6</sup>

In 2021, a comprehensive report by the World Economic Forum examined the barriers and enablers of implementing, adopting, and effectively utilizing diagnostics. This report highlights the crucial role of diagnostics in healthcare by guiding providers towards appropriate treatments and monitoring progress. However, barriers such as innovation, implementation, reimbursement, and accessibility limit their use, particularly in the LMICs. Increasing affordable access to essential diagnostics globally requires exploring innovative solutions and business models, harmonizing regulatory requirements, improving diagnostic performance through user input and contextual awareness, addressing data privacy and access issues, and aligning reference data with the target population.

The World Economic Forum Global Future Council on Biotechnology recommends strengthening existing initiatives and establishing a global alliance for affordable diagnostics to improve individual patient care and global health outcomes.





## 8. Accelerating access to diagnostics during the pandemic: The Lancet Commission on diagnostics (2021)<sup>7</sup>

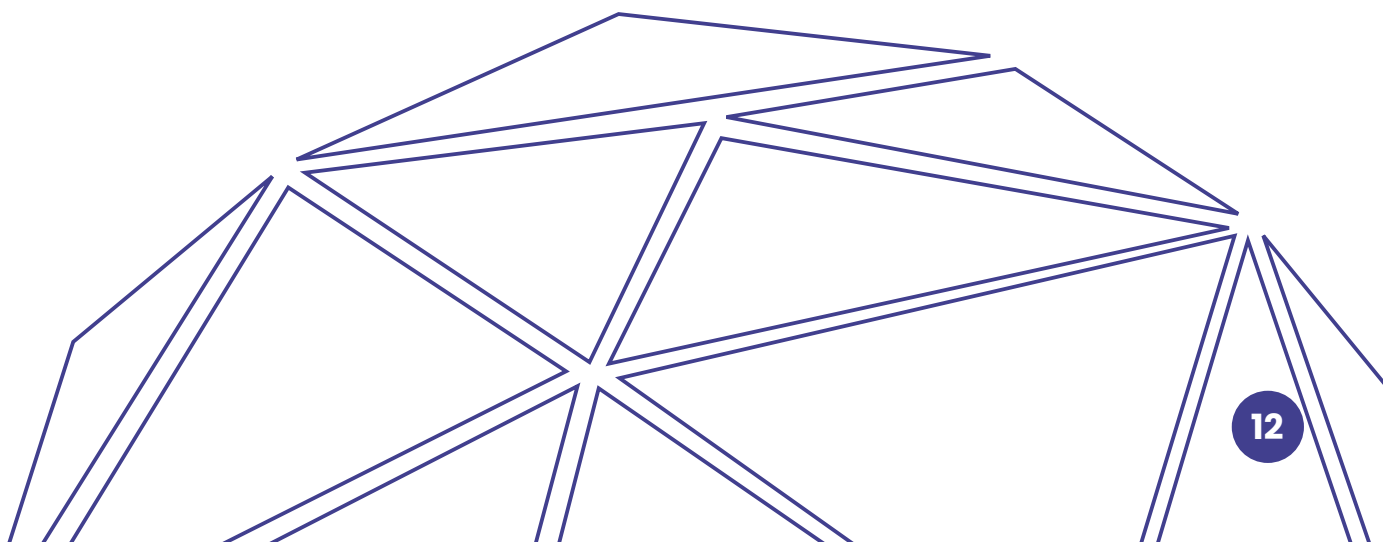
**The pandemic highlighted the crucial need for timely and accurate diagnosis, revealing the widespread scarcity and inequitable access to diagnostic testing in pathology, laboratory medicine, and diagnostic imaging.**

The heightened awareness brought by the pandemic presented an opportunity for change for laboratory strengthening. A Lancet commission was established in 2021 to assess the challenges and provide recommendations. The Commission on Diagnostics analyzed the state of diagnostics, revealing significant diagnostic gaps in the care pathway and limited access to diagnostics, particularly in primary healthcare and for marginalized populations. **It estimated that nearly half of the world's population lacked adequate access to diagnostics, emphasizing the urgent need for improvement and increased political will to address these challenges.**

## 9. Harnessing Value of Diagnostic Technologies during Crisis: Lessons from the COVID-19 Pandemic (2022)<sup>8</sup>

The pandemic has highlighted the critical role of access to modern testing and diagnostics, leading to a renewed appreciation for their value in Asia Pacific region as well. Diagnostic technologies have played a crucial role in disease monitoring, early identification of viral strains, and facilitating the resumption of operations for businesses. The Asia-Pacific Medical Technology Association (APACMed) published a report highlighting the value of medical diagnostic technologies during the pandemic and beyond. The report aims to promote greater recognition of the importance of these solutions, aligning with the WHO's Essential Diagnostics List and the Lancet Commission's report on transforming access to diagnostic technologies.

**The recommended actions include leveraging the momentum created by COVID-19 to measure the value of diagnostics, conducting comparative analyses, harmonizing technology review processes, allocating resources appropriately, prioritizing screening and diagnostics, and driving transparent investment and coverage schemes.**





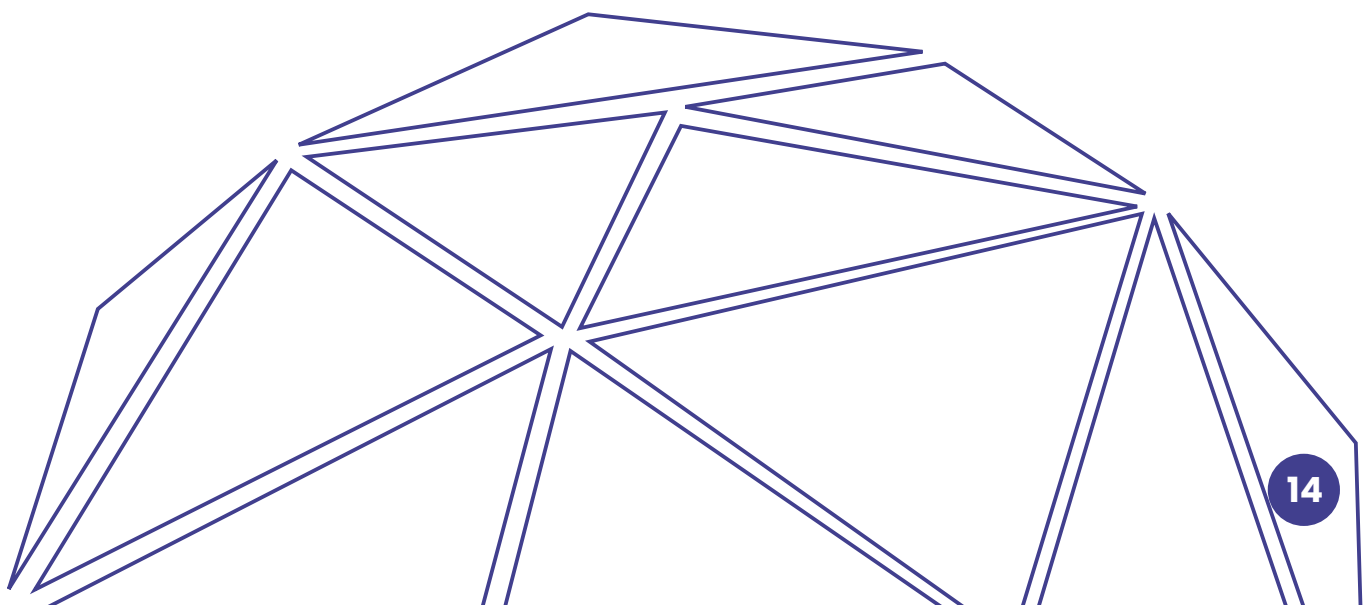
## 10. Strengthening Lab Systems: The ILSS Catalytic Initiative for Enhanced Readiness (2023)<sup>9</sup>

In 2023, the global effort continued to support advancements in laboratory capacities. The Global Fund extended its support to sub-Saharan Africa, Southeast Asia and Latin America to strengthen laboratory capabilities and respond effectively to epidemics.

The Integrated Laboratory Systems Strengthening (ILSS) Catalytic Initiative, implemented during the 2023-2025 allocation period (Grant Cycle 7), aims to enhance lab systems readiness to detect and respond to pandemic-related health threats. The initiative supports ten countries through the Strategic Initiative, nine countries through Matching Funds, and two regional bodies through multi-country grants. Process and administrative changes have been made, including notifying eligible countries in their allocation letters, allowing simultaneous technical assistance (TA) planning, and emphasizing coordinated planning of disbursements and procurement. The ILSS Catalytic Initiative aims to strengthen laboratory systems and improve response capabilities.

## 11. Case Example of Industry Collaboration To Strengthen Laboratory Systems for HIV and Tuberculosis Epidemics (2023)<sup>10</sup>

Recognising the sense of urgency, a leading industry player Roche has expanded its collaboration with the U.S. Centers for Disease Control and Prevention (CDC) to enhance laboratory capabilities in countries significantly affected by the HIV and tuberculosis (TB) epidemics. Through the 'Lab Networks for Health' Public-Private partnership, they aim to improve prevention, detection, and treatment outcomes by increasing laboratory human-resource capacity, supporting quality management systems, optimizing workflows, and enhancing pandemic preparedness through multi-pathogen testing capabilities. More such partnerships are needed between governments and private corporations to accelerate health systems strengthening and improve access to diagnostics for better disease management worldwide.







## 12. Conclusion

Advancing diagnostic capabilities has been a crucial focus in global health initiatives, recognizing the importance of quality-assured laboratory services in resource-limited settings.

Over the years, various challenges, gaps, and barriers have been identified in advancing laboratory systems, hindering the expansion of disease diagnosis and care services. Efforts to address these challenges have been made through international declarations, strategic frameworks, and initiatives emphasizing laboratory support integration into broader health systems. The establishment of the Model List of EDL and the Lancet Series PALM LMICs has further contributed to progress. However, significant gaps in access to quality diagnostics and laboratory capacity remain, particularly in primary healthcare and for marginalized populations.


The COVID-19 pandemic has highlighted the urgent need for improvement and increased political will for laboratory system strengthening. The unprecedented partnerships and collaborations made during the pandemic, can be leveraged to prioritize investment in laboratory systems. Continuing support for strengthening laboratory systems, scaling up successful programs, and addressing barriers to access and implementation are essential to ensure equitable and efficient healthcare delivery and universal health coverage.


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